英韓対訳

美國食品衛生法規

FEDERAL FOOD DRUG AND COSMETIC ACT

飜訳 金 碩 根

校閲 서울大学校 保健大学院
教授 鄭 文 植

Examinations and Investigations

Sec. 702 [372]. (a) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department. In the case of food packed in the Commonwealth of Puerto Rico or a Territory the Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this Act, the facilities at his disposal will permit of such inspection.

検査 및 調査

第702条〔372〕

(a) 保健教育厚生省長官은 이 法律의 目的을 為하여 保健教育厚生省의 官吏나 傭員 및 長官에 의하여 省의 官吏로서 正当하게 任命된 州와 準州 또는 行政下部組織의 保健食品薬品職員이나 傭員으로 하여금 検査와 調査를 시킬 수가 있다. 프에루토리코自治領이나 準州内에서 包装된 食品의 경우에는 長官은 스스로의 意見에 따라서 이 法律의 모든 条項의 施行에 関해 検査를 할수있는 施設이 있을 때는 合衆国入国의 最初地点에서 検査를 하도록 努力하여야 한다.

本項의 目的을 為해서 〔合衆国〕이란 州와 코롬비아特別区를 말한다.

For the purposes of this subsection the term "United States" means the States and the District of Columbia.

(b) Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

[*Regulations*] §*1.700 Examinations and investigations; samples.* (a) (1) When any officer or employee of the Department collects a sample of a food, drug, or cosmetic for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Department indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory. Only samples so designated by an officer or employee of the Department shall be considered to be official samples.

(2) For the purpose of determining whether or not a sample is collected for analysis, the term "analysis" includes examinations

(b) 食品, 薬品 및 化粧品이 이 法律에 立脚해서 採取된 場所에서 請求에 따라 物品의 標示에 姓名을 記載한 사람이나 所有者 또는 그 辯護士나 代理人에게 試驗이나 分析을 為한 公式 見本(샘플)의 一部를 提供하여야 한다.

但 長官은 이 法律条項의 適切한 行政을 為해서 必要하다고 認定될 때에는 規則으로서 本項에서 定하는 行為를 除外하든가 그 行為에 関해 期間과 条件을 붙일 수가 있다.

〔規則〕§1700 検査 및 調査, 샘플(見本)

(a)(1) 保健教育厚生省의 官吏나 傭員이 食品, 薬品 및 化粧品의 샘플을 이 法律의 規定에 따라 分析을 為해 採取할 때 이 샘플은 万一 그 샘플을 採取한 롯트가 州間去来에 提供되거나 譲渡된 것일것과 州間去来의 途中에 있거나 引受된 것이거나 또는 領域内에서 製造된것임을 明示하는 記録이나 証拠가 保健教育厚生省의 官吏나 傭員에 의해 얻어질 수 있다면 公式샘플이라고 指定된다.

保健教育厚生省의 官吏나 傭員에 의해 指定된 샘플만이 公式샘플이 된다.

(2) 샘플이 分析을 為해서 採取되었는지의 与否를 決定할 目的때문에 〔分析〕이란말은 検査 및 試驗을 包含한다.

and tests.

(3) The owner of a food, drug, or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

(b) When an officer or employee of the Department collects an official sample of a food, drug, or cosmetic for analysis under the act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless:

(3) 公式샘플을 採取한 食品, 藥品, 化粧品의 所有者란 샘플에 採取된 롯트를 所有하고 있는 사람을 가르킨다.

(b) 省의 官吏나 傭員이 이 法律의 規定에 立脚해서 食品, 藥品 및 化粧品의 公式샘플을 分析을 爲해採取할 때는 分析을 為해서 充分하다고 생각되는 量의 적어도 倍의 量을 採取하여야 한다. 但 다음 경우는 此限에 不在이다.

(1) The amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated;

(2) The cost of twice the quantity so estimated exceeds $ 10;

(3) The article is perishable;

(4) The sample is collected from a shipment or other lot which is being imported or offered for import into the United States:

(5) The sample is collected from a person named on the label of the article, or his agent, and such person is also the owner of the article;

(6) The sample is collected from the owner of the article, or his agent, and such article bears no label or, if it bears a label, no person is named thereon; or

(7) The analysis consists principally of rapid analytical procedures, organoleptic examination, or other field inspection examina-

(1) 샘플링을 為해서 使用할 수 있는 物品의 量이 分析에 必要한 量의 倍보다 적을 때.

(2) 分析에 必要한 量의 倍가 $10을 超過할 때.

(3) 物品이 腐敗되기 쉬울때.

(4) 샘플이 輸入되거나 合衆国에 輸入을 為해서 提供된 롯트에서 採取되었을 때.

(5) 샘플이 物品標示에 記載된 사람이나 그의 代理人부터 採取되고 그와같은 사람이 物品의 所有者일 때.

(6) 샘플이 物品의 所有者나 그의 代理人으로부터 採取되고 이와같은 物品이 標示가 없거나 標示가 있드라도 그 標示에 姓名이 記載되어 있지 않을 때.

(7) 分析은 原則的으로 샘플을 採取한 場所에서 하는 現場検査와 移動試驗室 이나 臨時試驗室에서 行하는 急速分析術式과 官

tions or tests, made at the place where the sample is collected or in a mobile or temporary laboratory. In addition to the quantity of sample prescribed above the officer or employee shall, if practicable, collect as part of the sample such further amount of the article as he estimates to be sufficient for use as exhibits in the trial of any case that may arise under the act based on the sample.

能 檢査를 包含한다.

前述한 샘플의 量에 부가해서 官吏나 傭員은 必要할 때에는 샘플에 関해서 이 法律에 의하여 提起될지도 모를 裁判에서 展示함에 充分한 量 을 採取하여야 한다.

(c) After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the act, or otherwise subject to the prohibitions of the act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, except when:

(c) 食品藥品局이 이와같은 食品, 藥品 또는 化粧品의 分析을 끝낸 다음에 分析結果 解釋에 있어서 物品이 이 法律이 意味하는 範圍內에서 不良 또는 不正標示品이며 이 法律의 禁止事項에 該當된다고 決定하고 이 샘플에 對한 法律에 立脚해서 提起될지도 모를 裁判에서 展示함에 充分한 量이 保管되어 있고 万若 量이 남아 있거든 샘플의 一部는 物品標示에 記載된 사람이나 그의 所有者 또는 辯護士나 代理人의 文書에 의한 要請이 있거든 分析을 為해 提供하여야 한다.

但 다음의 경우는 此限에 不在함.

(1) After collection the sample or remaining part thereof has become decomposed or otherwise unfit for analysis, or

(1) 샘플을 採取한 다음에 샘플이나 残存部分이 腐敗하거나 其他 理由로 分析에 不適合할 경우. 또는

(2) The request is not made within a reasonable time before the trial of any case under the act, based on the sample, to which such person or owner is a party. The person, owner, attorney, or

(2) 要請은 샘플에 関해서 法律에 의한 裁判以前에는 하여서는 아니된다.

샘플의 一部交付를 要請하는 사람, 所有者, 辯護士 및 代理人은 希望하는 量을 明

agent who requests the part of sample shall specify the amount desired. A request from an owner shall be accompanied by a showing of ownership, and a request from an attorney or agent by a showing of authority from such person or owner to receive the part of sample. When two or more requests for parts of the same sample are received the requests shall be complied with in the order in which they were received so long as any part of the sample remains available therefor.

記하여야하며 所有者가 要請할 때에는 그 所有権을 明示하여야 한다. 弁護士나 代理人이 要請할 때에는 物品標示에 姓名이 記載된 사람이나 所有者로부터 샘플을 引受할 権限을 賦与받은 것을 明示하여야 한다. 같은 샘플에 対해둘 또는 그 以上 要請이 있었을 때는 샘플이 利用될 수 있는 量이 남아 있는 限은 接受順序에 따라서 呼応해 주어야 한다.

(d) When an official sample of a food, drug, or cosmetic is the basis of a notice given under section 305 of the act, or of a case under the act, and the person to whom the notice was given, or any person who is a party to the case, has no right under paragraph (c) of this section to a part of the sample, such person or his attorney or agent may obtain a part of the sample upon request accompanied by a written waiver of right under such paragraph (c) from each person named on the label of the article and owner thereof, who has not exercised his right under such paragraph (c). The operation of this paragraph shall be subject to the exceptions, terms, and conditions prescribed in paragraph (c) of this section.

(d) 食品, 薬品 및 化粧品의 公式샘플이 이 法律의 第305条의 通告의 基礎가 되었을 경우와 이 法律에 立脚한 粉争의 根源일 경우로서 通告를 받은 사람이나 粉争에 関係있는 사람이 (c)項의 規定에 의한 権限을 갖고 있지 않을 경우는 이와같은 사람이나 그외 弁護士와 代理人은 物品標示에 姓名이 記載된 사람이나 所有者가 (c)項의 権利를 行使하지 않을 때 그들로 부터 (c)項의 権利를 抛棄한다는 뜻의 文書를 添付해서 샘플의 一部를 入手할 수가 있다.

本項의 実施는 (c)項에서 規定한 除外例 期間과 条件을 前提로 한다.

(e) The Food and Drug Administration is authorized to destory:

(1) Any official sample when it determines that no analysis of such sample will be made;

(2) Any official sample or part thereof when it determines that no notice under section 305 of the act,

(e) 食品薬品局은 다음과 같은 것을 廃棄시킬 수가 있다.

(1) 分析을 하지 않는다고 決定된 公式샘플.

(2) 이 法律의 第305条에 의한 通告가 없거나 이 法律에 立脚한 粉争이 行하여지

and no case under the act, is or will be based on such sample;

(3) Any official sample or part thereof when the sample was the basis of a notice under section 305 of the act. and, when after opportunity for presentation of view following such notice, it determines that no other such notice, and no case under the act. is or will be based on such sample;

(4) Any official sample or part thereof when the sample was the basis of a case under the act which has gone to final Judgment, and when it determines that no other such case is or will be based on such sample;

(5) Any official sample or part thereof if the article is perishable;

(6) Any official sample or part thereof when, after collection, such sample or part has become decomposed or otherwise unfit for analysis;

(7) That part of any official sample which is in excess of three time the quantity it estimates to be sufficient for analysis.

(c) For purposes of enforcement of this Act. records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department of Health, Education, and Welfare duly authorized by the Secretary to make such inspection.

(d) The Secretary is authorized and directed, upon request from the Commissioner of Patents, to furnish full and complete infor-

지 않는 것이 이와같은 샘플에 의해서는 이루어지지 않음을 決定한 公式 샘플이나 그 部分.

(3) 샘플이 이 法律의 第305条에 의거한 通告의 基礎이며 그 通告에 이어서 検閲에 提供된 機会后에 이 샘플에

對해서는 따로 通告는 안하며 또한 法律에 立脚한 粉爭이 行하여지지 않음이 決定된 公式 샘플이나 그의 部分.

(4) 샘플이 最終判決이 이루어진 이 法律에의한 粉爭의 基礎이며, 이 샘플에 의해서는 이 以上 粉爭이 일어나지 않는다고 決定됐을 경우의 샘플이나 그의 部分.

(5) 物品이 腐敗되기 쉬울 경우의 公式 샘플 또는 그의 部分.

(6) 採取한 然後에 腐敗하거나 分析으로 不適合하게된 公式 샘플이나 그의 部分.

(7) 分析에 充分한 量의 3倍를 넘는 公式 샘플의 部分.

(c) 이 法律을 施行할 目的때문에 政府의 어떤 省 또는 그의 執行機關의 記錄도 保建敎育厚生省長官에 의하여 檢査를 하도록 正當하게 權限을 賦與받은 保建敎育厚生省官吏의 檢査를 爲해서 開放되어야 한다.

(d) 保建敎育厚生省長官은 特許委員會要請이 있을 때는 特許委員會가 提出하는 藥品에 關한 特許申請에 關한 質問에 關해서 完全한 情報를 提供할 權

mation with respect to such questions relating to drugs as the Commissioner may submit concerning any patent application. The Secretary is further authorized, upon receipt of any such request, to conduct or cause to be conducted, such research as may be required.

限을 갖는다. 長官은 그 위에 이와같은 要請을 接受했을 때는 必要하다고 보는 硏究를 하거나 하도록하는 權限을 갖는다.

Seafood Inspection

Sec. 702a [372a]. The Secretary of Health, Education, and Welfare, upon application of any packer of any seafood for shipment or sale within the jurisdiction of this Act, may, at his discretion, designate inspectors to examine and inspect such food and the production, packing, and labeling thereof. If on such examination and inspection compliance is found with the provisions of this Act and regulations promulgated thereunder, the applicant shall be authorized or required to mark the food as provided by regulation to show such compliance. Services under this section shall be rendered only upon payment by the applicant of fees fixed by regulation in such amounts as may be necessary to provide, equip, and maintain an adequate and efficient inspection service.

Receipts from such fees shall be covered into the Treasury and shall be available to the Secretary of Health, Education, and Welfare for expenditures incurred in carrying out the purposes of this section, including expenditures for salaries of additional inspectors when necessary to supplement the number of inspectors for whose salaries Congress has appropriated. The Secretary is hereby authorized to promulgate regulations

海産食品의 檢査

第702a條〔372 a〕保建敎育厚生省長官은 이 法律이 定한 權限範圍內에서 出荷 또는 販賣를 위한 海産食品製造者의 要請이 있을 때는 自己判斷으로 그 食品과 生産, 製造 및 標示를 檢査하기위해서 檢査官을 指定할 수가 있다.

萬若 이와같은 檢査로서 이 法律이나 그에 따라 公布된 規則에 適合되어 있음이 判明되었을 때는 申請者는 食品의 規則에 의거 定해진것처럼 이와같이 適合하다는 것을 나타낼 마아크를 붙이도록 許可하거나 要求한다.

本條에서 定한 檢査官의 指定은 充分하고 效果的인 檢査를 하도록 設備가 갖추워져 있으며 또한 이를 維持함에 必要한 額數와 規則으로 定해진 費用을 申請者가 支拂할 경우에만 부과된다.

이와같은 料金은 財務省에 納入되며(國庫收納)保建敎育厚生省이 本條의 目的을 遂行하기 위해서 檢査官의 數를 追加하는 것이 必要한 경우에 議會가 이에 充當할 人件費를 包含시켜 必要로하는 費用에 利用할수가 있다.

長官은 이와같은 일이 接受되고 維持되거나 本條의 目的을 遂行하기 爲해서 衛生條件이나 기타條件을 定하는 規則을 公布할 權限을 갖는다. 本條와 本

governing the sanitary and other conditions under which the service herein provided shall be granted and maintained and for otherwise carrying out the purposes of this section. Any person who forges, counterfeits, simulates or falsely represents, or without proper authority uses any mark, stamp, tag, label, or other identification devices authorized or required by the provisions of this section or regulations thereunder, shall be guilty of a misdemeanor, and shall on conviction thereof be subject to imprisonment for not more than one year a fine of not less than $1,000 nor more than $5,000 or both such imprisonment and fine.

條때문에 定하여진 規則各項에 의해서 認定된 마아크, 스탬프, 標札, 기타 標示와 識別의 圖案을 僞造또는 模造하거나 類似(흉내내는)하게 만든것 또는 虛僞의 表現을하거나 權限이 없으면서 使用한 사람은 有罪가 되며 有罪宣告에 따라서 1個月以下의 懲役 또는 1,000$以上 5,000$以下의 罰金 또는 兩者를 併課한다.

Records of Interstate Shipment

Sec. 703 [373]. For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates:

Provided, That evidence obtained under this section shall not be used

州間去来의 記録

第703條〔373〕이 法律施行을 위해서 州間去來에 있어 運搬者, 州間去來에 있어서 食品, 藥品, 用具 및 化粧品을 引受하는 사람이나 이와같이 引受한 物件을 保持하고 있는 사람은 長官에 의해서 正當하게 指定된 官吏나 傭員이 要求할때에는 이와같은 官吏나 傭員에게 適當한 때에 食品, 藥品, 用具 및 化粧品의 州間去來에 있어서 移動이나 그의 移動間에 있어서나 그 後의 保持 및 數量, 出荷者와 더욱 受取人을 밝히는 모든 記録을 閲覽시키거나 複寫를 許容하여야 한다.

이와같은 運搬者等에 있어 官吏의 要求가 食品, 藥品, 用具 및 化粧品의 種類를 明記한 文書에 의해서 行하여졌을 때는 記録을 閲覽 또는 複寫를 許容치 않는다면 違法이다.

但 本條規定에 의하여 얻어진 證據는 그것을 提供한 사람의 刑事上告發에 써서는 안된다. 그 위에 또한 運搬者는 普通 運搬者로서의 일이 코스로서,

in a criminal prosecution of the person from whom obtained: Provided further, That carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

食品, 藥品, 用具 및 化粧品을 受領, 運搬, 保持또는 配達한 理由로 해서 이 法律 條項에 該當시킬 수는 없다.

Factory Inspection

Sec. 704 [374]. (a) For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce;

工場監視

第704條[374]

(a) 이 法律을 施行하기 위해서 保建敎育厚生省長官에 의해 正當하게 指定된 官吏나 傭員은適當한 方法으로 身分을 밝히고 所有者, 運營者 또는 管理者에게 文書로서 通知를 한 然後에

(1) 州間去來에 供與 또는 供與된 後에 食品, 藥品, 用具 및 化粧品이 製造, 處理, 包裝 되거나 保管되고 있는 工場, 倉庫 또는 建物에 適當한 때에 立會 또는 州間去來途上에 있는 食品, 藥品, 用具 및 化粧品을 運搬, 또는 保管에 使用된 車輛에 立會할 수 있는 權限을 갖는다. 그리고

and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. In the case of any factory, warehouse, establishment, or consulting laboratory in which prescription drugs are manufactured processed, packed, or held,

(2) 適當한 때, 適當한 制限과 適當한 方法으로 이와같은 工場, 倉庫, 施設과 모든 付屬物, 完成品, 未完成品 및 그들의 표시事項을 檢査할 수 있는 權限을 갖는다.

處方藥을 製造, 處理, 包裝 또는 保持하는 工場, 倉庫 및 硏究所에 對한 檢査에 있어서 檢査는 그處方藥이 이 法律이 意味하는 範圍內에서 不良 또는

inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs which are adulterated or misbranded within the meaning of this Act, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this Act, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this Act.

不正標示의 것인지 또는 이 法律의 어떤 條項에 의해서도 製造되지않았다든가 州間去來에 供與, 販賣되지 않는지 또는 販賣를 위해서 提供되고 있지 안았는지 等에 關해서 또는 이 法律에 違反해서 이와같은 場所에서 製造, 處理, 包裝, 輸送 保管되었는가에 關해서 그 施設內 모든 것(記録, 綴, 書類, 豫定表, 行政, 管理 및 設備를 包含함)에 걸처서 따저보아야 한다.

No inspection authorized for prescription drugs by the preceding sentence shall extend to (A) financial data, (B) sales data other than shipment data, (C) pricing data, (D) personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Act), and (E) research data (other than data, relating to new drugs and antibiotic drugs, subject to reporting and inspection under regulations lawfully issued pursuant to section 505 (i) or (j) or section 507 (d) or (g) of this Act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505 (j) of this Act).

處方藥의 경우, 前述한 檢査權限은 다음 各號에는 該當되지 않는다.

(A) 經濟上의 데이타

(B) 出荷以外의 販賣데이타

(C) 價格決定을 위한 데이타

(D) 人事上의 데이타(但 이 法律에서 定해진 機能을 遂行하기 위한 技術上 또는 職業上의 資格에 關한 데이타 以外의 것)

(E) 研究데이타(但 이 法律 第505條(i) 項 및 (j) 項 또는 第507條(d) 項 및 (g) 項에 의거 定하여진 規則에 의한 報告나 檢査를 받도록 規定되어 있는 新藥과 抗生物質에 關한 以外의 것)

A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to—

檢査에 있어서는 每回마다 通知를 해야하나 그의 檢査期間內라고하면 立會時마다 하지않아도 無妨하다.

各 一回의 檢査는 迅速하게 始作하고 完了시켜야 한다. 둘째번 文章의 各項은 다음 各號에는 適用되지 않는다.

(1) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs, upon prescriptions of practitioners licensed to administer such drugs to patients under the care of such practioners in the course of their professional practice, and which do not, either through a subsidiary of otherwise, manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of their business of dispensing or selling drugs retail;

(2) practitioners licensed by law to prescribe or administer drug and who manufacture, prepare, propagate, compound, or process drugs solely for use in the course of their professional practice;

(3) persons who manufacture, prepare, propagate, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale;

(4) such other classes of persons as the Secretary may be regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(b) Upon completion of any such inspection of a factory, warehouse,

(1) 藥業과 醫業의 開業을 規定하는 地方의 該當 法律에 따라서 施設을 維持할 藥局에서 그의 醫療行爲로서 患者에게 藥을 投與할 免許를 갖인 開業醫의 處方等에 따라 正當하게 處方藥을 調劑하는 일에 從事하고 이 正規調劑 또는 藥品小買

以外에 販賣를 위해서 藥品을 製造, 調製, 增殖, 合成, 處理하지 않는것.

(2) 法律에 따라서 藥品을 處方하여 投與할수 있는 免許를 갖인 開業醫로서 그의 醫療行爲 過程에서만 藥品을 製造, 調劑, 增殖, 合成 또는 處理하는 것.

(3) 藥品을 研究, 敎育 또는 化學分析만을 위해서 製造, 調劑, 增殖, 合成 또는 處理되는 것으로서 販賣는 하지 않는것.

(4) 公衆衛生을 지키기 위해서 本項을 適用할 必要가 없는 사람으로서 長官이 規則에 따라 本項의 適用을 除外시킨 사람.

(b) 檢査官은 工場, 倉庫, 研究室 또는 딴 施設의 檢査를 끝마치고 構內를 떠나기 前에 所有者,

consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary.

操作者 또는 代理人에게 文書를 갖이고 檢査官判斷에 의하여 이들 施設에서의 食品, 藥品, 用具 및 化粧品이

(1) 그의 全部 또는 一部가 不潔하거나 腐敗되어있거나 變敗되있는 物質을 含有하고 있거나

(2) 不潔한 것에 의하여 汚染되거나 그에 의하여 사람의 健康을 害칠만큼 非衛生的狀態에서 製造되고, 包裝되거나 保管되어 있든가?

에 對해서 觀察한 狀態를 通告하여야한다.
그리고 이 報告書의 寫本을 迅速히 長官에게 送付해야 한다.

(c) If the officer or employee making any such inspection of a factory, warehouse, or other establishment has obtained any sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(c) 工場, 倉庫 또는 딴 施設의 檢査를 하였든 官吏나 傭員이 檢査과정에서 샘플(標本)을 採取했을 때는 檢査가 完了하고 構內를 떠나기 前에 所有者, 運營者 또는 代理人에게 샘플을 採取하였다는 受領證을 주어야 한다.

(d) Whenever in the course of any such inspection of a factory or other establishment where food is manufactured, processed, or packed, the officer or employee making the inspection obtains a sample of any such food, and an analysis is made of such sample for the purpose of assertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the results of such analysis shall be furnished promptly

(d) 食品의 製造, 處理 또는 包裝施設과 工場檢査에서 檢査를 하였든 官吏나 傭員이 食品의 샘플을 採取하고 이와같은 食品, 藥品의 全部또는 一部가 不潔하거나 腐敗하고 있거나 變敗하고 있는가를 確認할 目的으로하거나 食品으로서 不適하다든가를 確認할 目的으로 分析이 이루어졌을 경우에는 이와같은 分析結果의 寫本을 迅速하게 所有者, 運營者 또는 代理人에게 주어져야 한다.

to the owner, operator, or agent in charge.

Publicity

Sec. 705 [375]. (a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health, or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

弘 報

第705條〔375〕

(a) 長官은 이 法律에 의한 모든 裁判, 判決 및 裁判所의 命令等과 起訴理由 및 處分을 包含해서 이를 要約한 레포트(公知事項)을 隨時로 發行하여야된다.

(b) 長官은 切迫한 健康上의 危害와 消費者에 對한 大規模的인 詐欺가 있다고 보았을 때에는 그 狀態를 包含해서 食品, 藥品, 用具 및 化粧品에 關한 情報를 配付하여야 한다.

Listing and Certification of Color Additives for Food, Drugs, and Cosmetic

食品, 藥品 및 化粧品에 使用할 色素添加物의 目錄記載와 許可

WHEN COLOR ADDITIVES DEEMED UNSAFE

Sec. 706 [376]. (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe

色素添加物이 不安全한 경우

第706條〔376〕

(a) 色素添加物은 食品, 藥品 및 化粧品이 어떠한 目的으로든 使用함에 있어서는(使用하게끔 되어 가거나 使用할려고 意圖하거나 適合한 것으로 되도록 함

for the purposes of the application of section 402(c), section 501(a)(4), or section 601(e), as the case may be unless—

에 對해서) 第402條(c)項, 第501條(a)項4와 第601條(e)項의 適用目的 때문에 다음 各號에서든 경우를 除外하고는 安全치 못하다고 看做된다.

(1)(A) there is in effect, and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additvie may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has with respect to such use, been exempted by the Secretary from the requirement of certification: or

(1) (A) 本條 (b)項에 따라서 添加物이 安全하게 使用할 수가 있는 條件을 記述한 條項을 包含해서 使用法에 對한 添加物의 指定規則에 그 添加物과 使用法이 適合할것, 또

(B) (i) 使用法에 關하여 (c)項에 의거 定하여진 規則에 따라 許可된 밧치(1回分)로 부터의 添加物, 또는

(ii) 어떤 用法에 關해서 許可를 必要로 하지안는다고 長官이 除外한 添加物, 또는

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsection (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)).

(2) 本條(f)項에서 定한 添加物과 指定除外에 該當하는것.

色素添加物에 關한 本條의 (b)項과 (c)項에서 定하는 規則과 이와같은 添加物에 關한 (f)項에서 定하는 除外規則이 發效하고있는 동안은 이와같은 添加物을 包含한다는 理由로서 食品의 경우는 第402條(a)項 1節意味範圍內에서 또는 染髮劑(第601條(a)項最後章에 記述되어있는) 以外의 化粧品의 경우는 第601條(a)項意味範圍內에서 不良하다고 보아서는 안된다.

LISTING OF COLORS

(b) (1) The Secretary shall, by regulation, provide for separately listing color additvies for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

(2) (A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

(3) Such regulations shall, to the deemed unsafe, and shall not be listed, for any use which will or may or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used;

色素의 目錄記載

(b) (1) 長官은 適當하며 안전한 範圍의 使用法에 關해서 食品에 쓰이는 色素添加物, 藥品에 쓰이는 色素添加物과 化粧品에 쓰이는 色素添加物을 따로따로 目錄에 收錄하고 規則에 따라서 指定하여야 한다.

(2)(A) 이 規則은 長官이 그 色素添加物 使用이 適當하고 그 使用法이 安全하다고 認定될때에는 食品, 藥品 및 化粧品에서 各各 全般的으로 使用하는 것으로서 (用法에 制限을 부과하지않고) 色素添加物을 目錄에 收錄할 수가 있다.

(B) 萬一 長官에게 提出된 데이타-가 (A) 項에서 말하는 目錄에 收錄하기 위해서 充分한 要件을 充足치 못한다면 또는 用法을 限定시켜서 目錄에 揭載할것을 申請하는 것이라면 適當하고 安全하다는 用法을 限定시켜 目錄에 收錄할 수가 있다.

(3) 이와같은 規則은 色素添加物目錄에 收錄한바 使用法에 있어서 安全性을 確保함에 必要하다고 長官이 認定하는 範圍에서 安全하게 使用할 수 있는 狀態를 記述하여야 한다. (이는 色素를 使用하고저 하는 物質에 있어서 色素의 量과 殘存量에 關한 最大許容量에 關한 基準과 使用方法에 關한 基準이나 使用法, 標示 및 包裝基準을 包含한다).

specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: Provided, however, That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term "food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

(4) 長官은 提出되어온 데이타가 그使用狀態下에서 安全하다는것을 表示하지않는 限은 提案된 使用法에 對해서 色素添加物을 目錄에 收錄해서는 않된다.

但 色素添加物이 食品에 對하여 使用하고자 하는 目錄收錄目的上 安全하며 長官이 第201條(s)項 에서 定한 有資格專門家에 의하여 一般的으로 意圖하는 使用法에 있어서 安全하기 때문에 〔食品添加物〕이라는 語句에서 除外한 物質이라는 것을 公表된 所見이 있을 때는 此限에 不在함.

(5) (A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(5) (A) 이 條項의 目的을 위해 色素添加物에 對하여 申請된 使用法이 安全한가 어떤가를 決定하기 위해서 長官은 다음과 같은 要素를 考慮하여야 한다.

(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive.

(i) 그 色素添加物을 使用하므로해서 食品, 藥品 및 化粧品의 內部나 表面에 發生하는 物質을 攝取하게되거나 또는 이들에 對하여 皮膚를 露出시키게 되는일.

(ii) 사람 또는 動物의 食餌속의 이와같은 色素添加物의 蓄積作用, 會餌속의 物質이나 化學的 및 藥學的으로 關聯있는 物質에 對하여 考慮할것.

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(iii) 色素添加物目録收録을 申込한 使用法에 對한 安全性을 評價할 科學的訓練과 經驗있는 有資格專門家意見에 따른 動物實驗의 使用方法에 對하여 一般的으로 適當하다고 認定되고 있는 安全性要素.

(iv) the availability of any needed practicable methods of analysis for determining the identify and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

(iv) 다음에 든것의 必要한 定性 및 定量을 위한 實用的分析法이 利用可能한가?

(1) 純粹한 色素와 色素에 含有된 모-든 中間産物 또는 不純物.

(Ⅱ) 食品, 藥品 및 化粧品속 또는 表面의 色素添加物

(Ⅲ) 이와같은 色素添加物을 使用하므로해서 使用된 物質의 속(內部) 또는 表面에 發生하는 物質.

(B) A color additive (i) shall be deemed unsafe, and shall not be listed for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or atfer other relevant exposure of man animal to such additive, it is found by the Secretary to induce cancer in man or animal:

(B) 色素添加物은, (i) 長官이 사람이나 動物이 攝取하므로해서 癌을 發生하게하는 것이라고 認定할때 또는 長官이 이와같은 添加物이 食品속에 있어서 使用됨이 安全性을 評價하기 위해서 適當하다고되어있는 試驗의 結果, 사람이나 動物에게 癌을 發生케하는 것이라고 認定될 때에는 安全하지 못하다고 看做되어 이와같은 添加物의 全部 또는 一部를 攝取하는等의 用法에 對해서 目録에 收録해서는 아니된다.

(ii) 意圖한 使用法에 對해서 添加物의 安全性을 評價하기 위한 適當한 試驗後 또는 사람이

나 動物이 기타 方法으로 添加物에 曝露된 다음에 사람이나 動物에게 癌을 發生시키는 것이라는 事實을 長官이 認定하였을 때는 安全치못한 것으로 看做되며 이와같은 添加物을 攝取하는것같은 結果가 될 使用法에 對하여 目録에 収録해서는 아니된다.

Provided, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of the feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal.

但 (B) 號의 (i)은 食品生産을 위해서 飼育하는 動物의 飼料 原料로서 使用되는 添加物로서 標示에 記載된 使用法에 따라서 使用되고있음이 確實하고 飼料가 意圖하는 效果나 反對效果를 나타내는일 없고 屠殺된 다음에 動物의 食用部分에 殘存치 않으며 또한 살아 있는 動物에서 産生되는 食品에 殘存치 않는 것(規則에 따라 長官에게 認定받은 方法에 의하나 이 規則은 (d) 項에 의한 것은 않임)이 長官에 의하여 認定되었을 때는 適用시키지 않는다.

(C) (i) In any proceeding for issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 701(e) if placed in effect, may request, within the time specified in this subparagraph, that

(C) (i) 色素添加物을 目録에 収録하는 規則의 公布, 修正 또는 廢止(그것이 長官自身의 發想으로 開始되었거나 請願으로 始作되었거나)의 手續의 進行段階에서 이와같은 提案에 따라 또는 第701條 (e)項의(1)號에 따라 發行된 長官命令이 萬一 發效한다면 不利한 影響을 받게되는 請願者이거나 누구든지 이 條項에서 定하는 時期內에서 이 條項(B)號에 의거 提起되고 이와같은 提案이나 命令이 包含

the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

되어 더욱 科學的判斷을 要하는 問題에 關해서 報告나 勸告를 위해서 審議會에 付託하도록 請求할수가 있다.

이와같은 請求가 있을때든가 萬一 長官이 審議會에 付託하는것이 必要하다고 看做되거든 長官은 即時 이 條項 (D)號에서 定하는 審議會委員을 任命하고 (B)號에 의해 提起된 問題에 關한 모-든 데이타-를 제공하고 그것을 研究하여 報告와 勸告를 求하기 위해서 審議會에 付託하여야 한다.

申請을 提出한 사람이거나 또는 (C)號에 依해 問題를 審議會에 付託할 것을 請求한 사람과 保健敎育厚生省의 代表는 付託된 問題에 關해 審議會에 相談할 수 있는 權限을 가지며 이號에 의한 付託의 請求 또는 長官自身의 發想에 따른 付託은 長官命令의 公告가 있기에 앞서 어느 時點에서나 또는 公告後 30日以內에 이를 할 수가 있다.

(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a

(ii) 이와같은 付託後 60日以內에 또는 審議會가 必要하다고 看做할 때는 더욱 其後 30日 以內에 審議會는 長官이 提出한 데이타와 其他 데이타를 獨立시켜 檢討한 然後에 長官에 對하여 報告와 勸告를 모든 基礎的인 데이타-와 勸告의 基礎가 된 理

report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendation, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall be order confirm or modify any order therefore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

由說明과 같이 提出하여야 한다.

이 報告와 勸告의 寫本은 申請을 하였든 사람이나 審議會에 付託할것을 出願한 사람에게 迅速하게 供與되어야 한다.

이와같은 審議會의 報告提出後 30日以內의 期間內에 長官은 報告, 勸告, 基礎데이타 및 勸告의 基礎가 되었든 說明書와 그 問題에 關係가 있는 長官이 示達하였든 從前命令等을 包含한 모든 데이타를 充分히 考慮한 然後에 發行된 命令을 確認 하거나 修正하든가 또는 이와같은 從前의 命令이 나오지 않았을 때는 命令에 따라 申請이나 請願에 對해서 行動을 取하여야 한다.

(iii) Where—

(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

(II) a request has been made for referral of such proposal to an advisory committee; the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

(iii) (1) 이 條項(B)號의 理由때문에 長官이 이 條項의 規定에 따라 이미 規定되어있는 色素添加物은 収錄目錄에서 除外하도록 提案을 發議하며

(2) 이와같은 提案을 審議會에 付託하도록 要請이 있을 境遇에는 長官은 審議會가 이 條項 (iii)에서 規定한 報告와 勸告를 하고 이를 檢討할때 까지는 이 提案에 對하여 命令을 내려서는 아니된다.

但 命令을 내릴 必要가 있을만한 緊急事態라고認定될 때에는 此限에 不在함.

(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulation prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(D) 이 條項(C)號에서 定한 審議會는 全美國科學아카데미에서 選擇된 付託받은 問題에 關해서 有資格이며 또한 適當한 各種職業의 背景있는 專門家에 의하여 構成되어야 한다.

但 非能力인 경우든가 全美國아카데미에서 拒絶됐을 경우에는 長官은 審議會委員을 選定하여야한다.

審議會構成人員은 長官이 이를 定한다. 審議會委員은 審議會를 爲하여 實際消費한 時間에 對하여 長官이 規則으로서 定한 妥當한 金額의 日當을 그 일에 對한 報酬로서 받는다. 더욱 그가 사는 住居地에서 떨어져서 일을 할 때에는 必要한 旅費와 生活費를 補償받는다.

委員은 美合衆國政府職員任命과 報酬에 關한 法律의 딴 條項을 適用받지아니한다. 長官은 委員에 對하여 充分한 事務職員과 其他 助力을 提供하여야 한다. 또한 規則으로서 委員이 따라야하는 手續節次를 定하여야 한다.

(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding

(6) 長官은 萬若 提供된 데이타나 申請된 使用法이 이 法律에 違反하여 消費者를 欺瞞함을 促進시키는 것임을 示唆하거나 이 法律이 意味하는 範圍內에서 標示違反이나 品質惡化를 招來할 結果가 되는 것임을 示唆하거든 그의 申請된 使用法에 對하여 色

or adulteration within the meaning of this Act.

素添加物을 目錄에 收錄하여서는 아니된다.

(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

(7) 萬若 長官이 色素添加物이 申請된 使用法의 安全性을 確實히하기위해서 許容量의 制限을 設定할 必要가 있다고 判斷될 때에는 長官은

(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

(A) 提供된 데이타가 그의 添加物의 安全許容限度內에서 使用되었을 때에 意圖하는 效果를 達成할 수 없다는 것을 認定하거든 目錄에 收錄 해서는 아니된다.

(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

(B) 意圖한 效果를 얻고자 必要하다고認定되는 量보다 높은 水準으로 許容量制限을 設定하여서는 아니된다.

(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all uses proposed therefore and at the levels of concentration proposed, the Secrtary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account,

(8) 食品에 使用되어 消費되거나 사람의 身体에 使用되는 色素添加物의 總量을 考慮할때 萬若 長官이 提供된 데이타-가 申請된 모-든 使用法에 對해서 濃縮水準에서 安全하며 또한 色素添加物(또는 藥物關係色素添加物)로서 目錄에 收錄할 것을 許可할 수 있음을 示唆할 수 없다고 認定되면 長官은 이와 같은 添加物(또는 關聯添加物)을 目錄에 收錄하거나 收錄치않는 用途를 決定하기 위해서든가 企圖된 많은 使用法에 對해서 總安全許容量을 決定하기 위해서 딴 關聯因子속에서(그리고 安全의 主要基準에 對해서)다음과 같은 事項을 考慮하여 야한다.

among other relevant factors (and subject to the paramount criterion of safety).

(a) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses: (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

(A) 色素添加物(또는 關聯添加物)이 企圖된 使用法에 의해 包含된 物品의 市場流通性과 이 使用法에 關係있는 産業의 發展性.

(B) 食品에 使用되거나 사람의 身体에 여러가지 理由로서 使用되는 경우 色素添加物의 推定總量과 濃縮의 程度.

(C) 申請된 使用法에 對해서 適當하며 安全한 란 色素添加物이 있으며 그것을 利用할 수 있는지 또는 利用可能性有無

CERTIFICATION OF COLORS

色素의 許可

(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: Provided, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to

(C) 長官은 더욱 規則으로서 (i), (b)項의 規定에 따라 또는 (b)項의 規則에 對하여 定한 添加物에 對한 基準에 適合한 一團의 色素添加物을(安全한 稀釋劑와 같이 또는 稀釋劑없이)證明하는 것을 定하고 또한 (2)長官이 前號의 證明이 公衆衛生上必要치 않다고 認定될 때에는 이와같은 添加物, 또는 使用法의 目録収録을 前號의 許可로부터 除外할 것을 定하여야한다.

但 食品에 對한 使用에 關해서 目録에 収録된 色素添加物이(b)項(4)節의 但書의 理由로서 安全하다고 認定되고 公衆衛生上 必要치 않다고 認定될 때에는 此限에 不在임.

be necessary in the interest of public health protection.

PROCEDURE FOR ISSUANCE, AMENDMENT, OR REPEAL OF REGULATIONS

規則의 制定、改正 또는 廢止

(d) The provisions of section 701 (e), (f), and (g) of this Act shall, subject to the provisions of subparagraph (C) of subsection (b) (5) of this section, apply to and in all respects govern proceedings, for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judical review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

(d) 이 法律第701條(e), (f) 및 (g) 項은 本條(d)項(5)의 (c)節의 條件에 따라 이 條項의 (b)項과 (c)項 規定에 따라 定해진 規則을 制定하거나 改正하거나 廢止하는 手續(이 手續에서 長官의 行動에 對한 裁判上의 審査를 包含함)의 모든 点에 對해서나 이와 같은 手續 記錄의 謄本을 받아드림에 對하여 適用된다.

但 다음 경우에는 此限에 不在임.

(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day) by written notice to the petition, extent such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

(1) 萬若 手續이 請願申請으로서 始作되거든 長官은 그 申請後 30日以內에 請願으로 行하여진 提案의 公告를 一般用語로 印刷發行하여야 한다. 또 이와같은 提案에 對해서 執行되는 長官命令(第701條(e)項 : 第(1)號에 따라서 要求됨)은 審議會에 對하여 이미 付託(또는 付託의要請)되어 있지 않으면 이와같은 것은 申請日로부터 90日以內에 發行되어야 한다.

但 長官은 이 90日 以內에 文書로서 請願者에게 通告하고 請願을 檢討하고 調査함에 必要하다고 生覺되는 日數를 延長할 수가 있다. (但 請願申請日부터 180日을 超過해서는 아니된다.)

(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b)(5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006 (c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing:

(2) 本條(b)項(5)의 (D)節에 따라 任命된 審議會 委員에 의해서 長官에게 上申된 報告, 勸告, 基礎데이타와 理由는 行政手續法의 第7條 (C)項에 따라 萬若 關聯이 있고 重要하다면 聽聞記錄의 一部로 하여야 한다.

諮問審議會는 長官, 請願者 및 聽聞을 行하는 官吏의 要求에 따라서 聽聞會에 參席하고 審議會의 報告와 勸告에 關해서 證言하는 委員을 指名하여야 한다.

但 이는 其他 委員이 出席해서 證言하는 것을 妨害하는 것이여서는 않된다.

(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearings) shall be subject to the requirements of section 409(f) (2); and

(4) the scope of judical review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

(3) 公聽會後의 長官命令(公聽會에 앞서 提出된 反對意見에 對해서 行動하는)은 第409條 (f)項 (2)에 따라야만 한다.

(4) 이와같은 命令에 對한 裁判上의 審査 範圍는 第409條(g)項 (2)節의 넷째번 文章과 (3)節에 따라야만 한다.

FEES

(e) The admitting to listing and certification of color additives in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to pro-

料 金

(e) 이 法律의 規定에 따라 定하여진 諸規則에 따라서 色素添加物의 目錄收錄과 證明의 承認은 이와같은 目的에 對한 充分한 일을 하고, 維持하고 또 設備를 함에 必要하다고 해서 規則에 따라 定하여진 料金을 支拂함으로서만이 完結되는 것이다.

vide, maintain, and equip an adequate service for such purposes.

EXEMPTIONS

(f) The Secretary shall by regulations (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

例 外 規 則

(f) 長官은 色素添加物, 그의 使用法 및 그 添加物을 含有한 食品, 藥品 및 化粧品이 有資格 專門家에 의하여 研究用目的에만 使用되는것이며 또한 公衆保健에 違背되지 않는다고 믿어질때에는 規則에 따라 (d)項의 規定에도 不拘하고

本條諸規定의 適用을 除外하여야 한다.

This Act [the color additive amendments of 1960] shall, subject to the following provisions, take effect on the enactment date [July 12, 1960].

이法律〔1960年의 色素 添加物의 改正〕은 다음 條項에 關해서는 制定日字로부터 發效한다. 〔1960年 7月12日〕

PROVISIONAL LISTINGS OF COMMERCIALLY ESTBLISHED COLORS

(a) (1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act [the Federal Food, Drug, and Cosmetic Act] as amended by this Act. A provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or ex-

商業的으로 確立된 色素의 一時的인 目録収録

(a) (1) 이 條項의 目的은 一時的인 目録収録을 通해서 妥當한 期間, 暫定的인 베이스로서 商業的으로 確立되어있는 色素添加物의 使用을 基本的인 法律〔美聯邦食品, 藥品, 化粧品法〕의 規定에 依據 이와같은 添加物의 目録収録을 決定함에 基礎로서 必要한 科學的調査를 完成하기 까지 公衆保健에 違背되지않을 程度로 可能하게하는 것이다.

이 條에서 定하는 或種의 使用法에 對한 色素添加物의 一時的目録収録은〔一時的인 目録収録이라 看做되는것도 包含〕 本條規定에 따르는 편보다 短期間에 終結 또는 無效로되는 境遇以外에는

piring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 of the basic Act, whichever date first occurs.

(A) 終結日에(이는 이 項의 2號에 따라 定하여진다.)

(B) 基本法第706條에서 定한 어떤 使用法에 對한 이와같은 添加物의 目錄收錄이 有效하게된 日字에 있어서(A) (B) 어느쪽이 最初에 이러났을 때 有效期限이 終了된다.

(2) For the purposes of this section, the term "closing date" means (A) the last day of the two and one-half year period beginning on the enactment date or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or deemed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 of the basic Act. The Secretary may terminate a postponement of the closing date at any time if he finds that such

(2) 本條의 目的을 爲해서〔有效期限終了의 期日〕이란

(A) 最初發效日字로부터 2年半 經過한 最終日字. 또는

(B) 色素添加物 또는 그 使用法의 特別한 一時的目錄收錄에 關해서는(또는 一時的目錄收錄으로 看做되는것) 長官이 이 號의 權限에 따라 定할수있는 後日의 日字를 意味한다.

長官은 利害關係가있는 사람의 申請에 따르거나 長官自身의 發想에 의하여 本條에서 定한 特別한 色素添加物과 이와같은 添加物의 使用法을 一時的目錄收錄(또는 一時的 目錄收錄으로 看做되는것)에 關한 最初에 決定된 有效期限終了日字를 萬若 長官 判斷으로써 이와같은 行動이 基本法第706條에서 定한 添加物의 色素 또는 그 色素의 特別使用法收錄에 關한 決定을 함에 必要한 科學的調査를 完了시킬 目的에 一致한다면 本條目的을 實行함에 必要한 期間을 規定에 의하여 延期할 수가 있다. 長官은 萬若 延期를 認定할 수가 없다는 点을 發見하였을 때나 狀況變化로서 이와같은 延期理由가 이미 存在치 않을때 또는 이와같은 延期에 붙어진 經過報告書를 提出할 條件

postponement should not have been granted, or that by reason of a change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission to progress reports or with other conditions attached to such postponement.

이나 其他條件에 適應시킬 수 없을 때는 언제든지 有効期限의 期日延長을 終了시킬 수가 있다.

(b) Subject to the other provisions of this section—

(1) any color additive which, on the day preceding the enactment date, was listed and certifiable for any use or uses under section 406(b), 504, or 604, or under the third proviso of section 402(c), of the basic Act, and of which a batch or batches had been certified for such use or uses prior to the enactment date, and

(b) 이 條의 딴 條項에 따라

(1) 發効日字보다 以前의 日字에 基本的法律 第406條(b), 第504條 및 第604條, 또는 第402條(c)項의 세째번 但書에서 定한바 使用法에 對한 目錄에 収錄하고 證明할 수있는 色素添加物과 그 中에서 發効期日에 앞서 이와같은 使用法에 對하여 許可된 뱃치(一團). 그리고

(2) any color additive which was commercially used or sold prior to the enactment date for any use or uses in or on any food, drug, or cosmetic, and which either (A), on the day preceding the enactment date, was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

shall, beginning on the enactment

(2) 食品, 藥品 및 化粧品에 對한 使用法에 있어 發効日字 以前에 商業的으로 使用되었거나 販賣되고 있는 色素添加物로서 (A) 發効日 以前에 本項1號에 記述된 基本法條項範圍內의 物質이나 (B) 合成 베타캐로틴(β-carotine)으로 알려지고 있는 色素添加物은 發効期日에 本條規定에 따라 이와같은 使用法에 對한 色素添加物로서 一時的目錄에 収錄된것으로 看做된다.

date, be deemed to be provisionally listed under this section as a color additive for such use or uses.

(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406(b), 504, or 604 of the basic Act prior to the enactment date, although such color was no longer listed and certifiable for such use under such sections on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

(c) 누구의 請求가 있드라도 長官은 萬若 提供된 데이타에 의하여 公衆保健을 지킨다는 目的에 違背되지 않는다고 看做되면 色素添加物이 發効期日以前에 그 以上 目録에 収録되어 許可되지 않은 것이였다 하드라도 發効期日以前에 色素添加物은 目録에 収録된 使用法에 對해서 基本的法律第406條(b)項, 第504條, 第604條에 의거, 許可된 이와같은 物質의 뱃치(一團)을 一時的으로 目録에 収録한다. 이와같은 目録収録은 公告日로부터 發効한다.

(d) (1) The Secretary shall, by regulations issued or amended from time to time under this section—

(A) insofar as practicable promulgate and keep current a list or lists of the color additives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a particular use shall, in any proceeding under the basic Act, be conclusive evidence that such provisional listing is in effect;

(d)(1) 長官은 本條에 따라 施行 또는 改正된 規則에 의하여

(A) 色素添加物과 (b)項規定으로 一時的 収録을 하였다고 看做되는 色素添加物의 特定使用法의 目録이 現行것이며 實際的으로 公布되는 限에서는 또 特定使用法에 關하여 色素添加物이 目録에 存在한다고 함은 基本法의 어떠한 手續節次에 있어서도 이와같은 一時的収録이 有効하다고하는 決定的인 證據이다.

(B) provide for the provisional listing of the color additives and particular uses thereof specified in subsection (c);

(B) 色素添加物과 그의 (c)項에 의한 特定使用法의 一時的目録収録을 行하여야한다.

(C) provide, with respect to particular uses for which color additives

(C) 一時的으로 収録된 色素添加物이나 一時的으로 収録되었다고 看做되는 色素添加物의 特定使用法에 關해서 基本法律 第706條에 의거 目録収録을 公

are or are deemed to be provisionally listed. such temporary tolerance limitations (including such limitations at zero level) and other conditions of use and labeling or packaging requirements, if any, as in his judgment are necessary to protect the public health pending listing under section 706 of the basic Act;

衆保健上 保留시킬 必要가 있다고 判斷될 때는 暫定的인 許容制限(제로레벨을 包含)과 其他 標示나 包裝條件을 定하여야 한다.

(D) provide for the certification of batches of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b)(2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

(D) 本條規定에 따라 目錄에 收錄되거나 目錄에 收錄되었다고 看做되는 使用法에 對한 色素添加物의 뱃치(一團)의 證明을 (稀釋劑와 같이 또는 쓰지않고) 定해야한다. 但 本條(b)項(2)規定에 의거 一時的으로 目錄에 收錄된 色素添加物은 許容量制限에 該當되지 않는 것으로서 이와같은 許可를 免除되는 것으로 된다.

(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health.

(E) 公衆保健을 지킴에 必要하다고 判斷된 때에는 언제든지 即刻 色素添加物과 그의 特定 使用法의 一時的目錄收錄(또느 一時的 目錄收錄이라고 볼 수 있는것)을 終了시킬 것을 定하여야 한다.

(2) (A) Except as provided in subparagraph (C) of this paragraph, regulations under this section shall, from time to time, be issued, amended, or repealed by the Secretary without regard to the requirements of the basic Act, but for the purposes of the application of section 706(e) of the basic Act (relating to fees) and of determining the availability of appropriations of fees (and of advance de-

(2)(A) 本項(c)號에서 定한 경우를 除外하고 本條規定에 따라 定해진 規則은 基本法律의 딴 規定에도 不拘하고 長官에 의하여 臨機應變으로 施行되며, 改正되거나 廢止되어야 한다. 然而나 第706條(e)項의 適用目的을 위해서(料金에 關한)와 料金의 充當(料金을 카바하는 事前供託)의 有效性을 決定함에 있어 本條規定에 의한 手續節次, 規則 및 許可는 第706條

posits to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such sectoin 706. Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date were in effect pursuant to section 706 of the basic Act, shall be deemed to be regulations under such section, 706 as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 as in effect prior to the enactment date shall be available for the purposes specified in such section 706 as so amended.

規定에 따른 手續節次, 規則및 許可라 看做된다. 基本法律第706條에 의하여 發效期日以前에 有效하였든 料金(料金을 카바하는 事前供託)을 定하는 規則은 이 法律로서 改正된 第706條 規定에 따른 規則이라고 看做된다. 또 發效期日以前에 有效하였든 第706條에서 定한 目的이 利用可能한 料金의 充當(事前供託)은 第706條의 改正目的에 利用可能한 것이다.

(B) If the Secretary, by regulation—

(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1)(E) of this subsection; or

(ii) has pursuant to paragraph (1)(C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action, any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a)(2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action

(B) 萬若 長官이 規則에 따라

(i) 이 項(1)號 (E)에 따라 色素添加物이나 그의 特定使用法의 一時的目錄收錄(또는 一時的目錄收錄이라고 보여지는것)의 期限을 끝마쳤다.

(ii) 이미 有効하게된 一時的目錄收錄(또는 一時的目錄收錄으로 보이는것)에 關해서 本條(1)項(C)와 (3)項에 의거 長官이 自發的으로 더욱 嚴重한 許容量制限이나 딴 制限 또는 딴 要求를 定했을때에는 이와같은 措置로서 不利한 影響을 받게되는 사람은 누구든지 本條(a)項(2)의 (A)節에서 定한 期限이 지나기 以前에 長官에게 이와같은 行動을 廢止하거나 修正하도록하는 規則의 改正을 申請할 수가 있다. 然而나 이와같은 申請은 앞서말한 行動을 保留시키거나 停止시킬 수는 없다. 이와같은 申請은 規則으로

dence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701 (f) of the basic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

命令이 公聽會의 모든 記錄의 正當한 評價로서 支持되고 있을 때는 此限에 不在임. 裁判所의 審査結論이 나오기前에 命令을 保留시키거나 停止시키는 것같은 命令을 裁判所에서는 내려서는 아니된다.

(D) On and after the enactment date, regulations provisional listings, and certifications (or exemption from certification) in effect under his section shall, for the purpose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing a color additive, have the same effect as would regulations, listing, and certifications (or exemptions from certification) under section 706 of the basic Act. A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706 (b) or (c) of the basic Act.

(D) 發効期日과 其後의 本條規定에 의거 有効하게된 規則 一時的目錄收錄과 許可(또는 許可除外)는 物品이 基本法이 意味하는 範圍內에서 色素添加物을 含有하고 있다는 理由로 不良品이라거나 標示違反品인가의 與否를 決定할 目的으로 基本法第 706條規定에 의한 規則, 目錄收錄과 許可 (또는 許可除外)와 같은 効力을 갖는다.

本條規定에 의한 規則, 一時的目錄收錄이나 그 終結, 許容量制限, 許可 또는 許可의 除外는 基本法第706條(b)項, (c)項에 規定한 手續節次에서 推定 또는 推論의 基礎로 삼아서는 아니된다.

of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The secretary shall, after publishing such proposed and affording all interested persons and opportunity to present their views there on orally or in writing, act upon such proposal by published order.

서 提案된 改正點을 說明하는것이며 提案한 廢止 또는 修正이 公衆保健을 지킴에 一致한다고하는 데이타(長官에게 提供된 데이타에 言及하거나 長官이 公式的인 通知를 接受)를 包含시켜야 한다.

長官은 이와같은 提案을 公告하고 모든 關心 있는 사람들에게 意見을 口頭와 文書로서 應答할 수 있는 機會를 賦與한 다음에 命令의 公布로서 이와같은 提案에 對하여 行動을 取하여야 한다.

(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds of such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evi-

(C) 本項(B)號에 따라 公布된 命令때문에 不利한 影響을 받게되는 사람은 누구든지 그 公告後 30日 以內에 特히 命令속에서 反對하는 條項을 明白히 하고 그 反對에 對한 理由를 記述하여 長官에게 反對를 申立하고 이와같은 反對에 對한 公聽會를 開催하도록 要請할 수가 있다. 長官은 이와같은 反對에 對하여 公聽會를 開催하고 公聽會에서 採擇한 證據에 따라 命令의 公告로서 反對에 對한 行動을 取하여야한다. 이와같은 命令은 終了된 一時的 目錄收錄을 復活시키고 以前에 定해진 暫定許容量制限을 緩和시키거나 廢止시키고 또 上程된 證據가 公衆保健을 지킴에 一致한다고 判斷되었을 때에만 本項(1)과(3)號로서 定해진 딴 制限을 緩和시킬 수가 있다. 本號規定으로서 내려진 命令은 基本法第701條 (f)項에 따라 裁判所의 審査를 받어야한다. 但 長官은 意見과

(3) For the purpose of enabling the Secretasy. to carry out his functions under paragraphs (1) (A) and (C) of this subsection with respect to color additives deemed provisionally listed, he shall, as soon as practicable after enactment of this Act, afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1)(A), or for determining the prevailing level or levels of use thereof prior to the enactment date with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1)(C), the Secretary shall establish a temporary tolerance limitation at zero level for such use or uses until such time as he finds that it would not be inconsistent with the protection of the public health to increase or dispense with such temporary tolerance limitation.

(3) 長官이 一時的으로 目錄收錄이 되었다고 看做되는 色素添加物에 關해서 本項(1)號 (A), (C)에서 規定한 機能을 實行할것을 可能케하기 위하여 長官은 이 法律發効後 實行可能케 되면 即時 公告로서 關心을 갖고있는 사람에게 그에 關한 데이타를 提出할 適當한 機會를 賦與해야한다. 萬若 이와같이해서 提出된 데이타 또는 長官이 所持한 데이타가 (1)號 (A)에 의거 公布된 目錄에 收錄되어있는 色素添加物이거나 그의 特定使用法에 包含됨을 認定하기 위한 信賴할 수 있는 理由를 立證하지 않거나 (1)號 (C)에 規定한 暫定的許容量과 使用法에 對한 制限을 述懷할 目的으로 發効期日에 앞서서 一般的으로 使用되는 라 벨(標示書)와 使用法의 標示를 決定하기 爲한 信賴할 수 있는 基盤을 確立할 수 없을 때에는 長官은 이같은 暫定許容量制限을 緩和시키거나 廢止시킴이 公衆保健을 지키는 目的에 合致시킬 수 있음을 밑게 될때까지는 이같은 使用法에 對한 暫定許容制限을 제로 레벨(Zero level)로 定하여야 한다.

Revision of United States Pharmacopeia; Development of Analysis and Mechanical and Physical Tests

合衆国薬局方의 改正, 分析法, 機械的 및 物理的인 試驗法의 改正

Sec. 707 [377]. The Secretary, in carrying into effect the provisions of this chapter, is authorized hereafter to cooperate with associations and scientific societies in the revision of the United States Pharmacopeia and in the development of methods of analysis and mechanical and physical tests necessary to carry out the work of the Food and Drug Administration. [From the Labor-Federal Security Appropriation Act, 1944.]

第707條〔377〕

長官은 이 章의 各 條項을 實行하기 위해서 美合衆國藥局方의 改正과 食品藥品局의 業務를 實施하기 위해서 必要한 分析方法과 機械的 또는 物理的인 試驗法의 開發을 爲해 民間團体 또는 學術團体(各學會)와 協調를 할 수 있는 權限을 갖는다. 〔勞動 美聯邦安全法, 1944年부터〕

CHAPTER VIII - IMPORTS AND EXPORTS

第八章 輸入 및 輸出

Sec. 801 [381]. (3) The Secretary of the Treasury shall deliver to the Secretary of Health, Education, and Welfare, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Health, Education, and Welfare and have the right to intro-

第801條〔381〕

(a) 財務省長官은 保健敎育厚生省長官의 要請에 따라서 美合衆國에 輸入되거나 輸入用으로 提供되는 食品, 藥品 및 化粧品의 見本(샘플)을 提供하여야 한다. 또 그들에 對하여 保健敎育厚生省長官 앞으로 出頭하여야 하거나 이들에 關한 證據를 提供할 權限을 갖는 所有者나 荷受人에게 通知를 하여야 한다. 保

duce testimony. The Secretary of Health, Education, and Welfare shall furnish to the Secretary of the Treasury a list of establishments registered pursuant to subsection (i) of section 510 and shall request that if any drugs manufactured, prepared, propagated, compounded, or processed in an establishment not so registered are imported or offered for import into the United States, samples of such drugs be delivered to the Secretary of Health, Education, and Welfare, wi notice of such delivery to the own or consignee, who may appear befo the Secretary of Health, Educatic and Welfare and have the right introduce testimony.

健敎育厚生省長官은 第510條(i)項規定에 定해진 登錄施設의 目錄을 財務省長官에게 提供하여야하며 萬若 登錄된 施設以外의 施設에서 製造, 調劑, 增殖, 合成 또는 處理된 藥品이 美合衆國에 輸入되거나 輸入用으로 供與되었으면 保健敎育厚生省長官은 財務省長官에게 이같은 藥品의 見本을 保健敎育厚生省長官 앞으로 出頭 또는 證據를 提出할 權限을 갖인 所有者나 受取人에게 提出하도록 從憑하거나 要請하여야 한다. 萬若 이같은 見本의 試驗結果로서 또는 試驗에 따르지 않드라도 다음과 같은 것이 判明되었을 때에는 本條(b)項에서 定한 경우를 除外하고 輸入은 拒否되어야 한다.

If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission, except as provided in subsection (b) of this section. The Secretary of the Treasury shall cause the destruction of any such article refused admission unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within ninety days of the date of notice of such refusal or within such additional time as may be permitted pursuant to such regulations.

(1) 不潔한 狀態下에서 製造, 處理, 包裝되었을 경우,

(2) 그 物品의 生產, 輸出한 나라에서 禁止되거나 販賣가 制限되어 있는 경우.

(3) 그 藥品이 不良하며 不正標示로서 第 505條에 違反되어 있을 경우.

財務省長官은 自身(財務省長官)이 定한 規則에 따라서 輸入拒否通告後 90日以內 또는 이 規則에 따라 許容되는 그 以上의 追加期限內에 輸出되지않는 限, 輸入을 拒否한 것을 廢棄하도록 措置하여야 한다.

This paragraph shall not be con-

本項은 1922年 5 月26日 改正된 法律(美合衆國法律

strued to prohibit the admission of narcotic drugs the importation of which is permitted under section 2 of the Act of May 26, 1922, as amended (U.S.C., 1946 edition, title 21, sec. 173).

(b) Pending decision as to the admission of an article being imported or offered for import, the Secretary of the Treasury may authorize delivery of such article to the owner or consignee upon the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as may be required pursuant to regulations of the Secretary of the Treasury. If it appears to the Secretary of Health, Education, and Welfare that an article included within the provisions of clause (3) of subsection (a) of this section can, by relabeling or other action, be brought into compliance with the Act or rendered other than a food, drug, device, or cosmetic, final determination as to admission of such article may be deferred and, upon filing of timely written application by the owner or consignee and the execution by him of a bond as provided in section, the Secretary may, in accordance with regulations, authorize the applicant to perform such relabeling of other action specified in such authorization (including destruction or export of rejected articles or portions thereof, as may be specified in the Secretary's authorization).

All such relabeling or other action pursuant to such authorization shall in accordance with regulations be under the supervision of an officer or employee of the Department of Health, Education, and Welfare designated by the Secretary, or an officer or employee of the Department of the Treasury designated by the Secretary of the Treasury.

1946年, 法律第21號, 173條) 第2條規定에 의하여 許可된 麻藥輸入을 禁止하는 것으로 解釋해서는 아니된다.

(b) 輸入되거나 輸入用으로 供與되는 物品輸入許可에 關한 決定이 保留되고 있을 때에 財務部長官은 그의 規則에 따라 要求되는 措置를 物品의 所有者 또는 荷受人이 履行치 않는 경우에 損害를 淸算할 費用에 充當시키기 爲해 良質로서 充分한 擔保를 設定한다면 그 物品은 所有者 또는 荷受人에게 引渡할것을 許可할 수가 있다.

萬若 保健敎育厚生省長官이 本條(a)項(3)節의 範圍內의 物質이 標示의 變更이나 其他 行爲로서 法律에 適合하다고 生覺될 때 또는 食品, 藥品, 器具 및 化粧品以外의 것으로 할때에는 그 物品의 輸入許可에 關한 最終決定을 保留하고 所有者 또는 荷受人이 文書로서 申請하고 本項에서 前述한 擔保設定을하였으면 長官은 申請者로하여금 標示의 變更이나 其他 行動(廢棄나 再輸出 및 長官이 許可하는 그中 一部를 包含)을 規則에 따라서 遂行시킬 수가 있다.

모든 이와같은 標示의 變更이나 其他 行動은 保健敎育厚生省長官이 任命하는 保健敎育厚生省官吏나 職員, 또는 財務省長官이 任命한 財務省官吏나 職員의 監督下에서 規則에 따라서 行하여져야 한다.

(c) All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of the relabeling or other action authorized under the provisions of subsection (b) of this section, the amount of such expenses to be determined in accordance with regulations, and all expenses in connection with the storage, cartage or labor with respect to any article refused admission under subsection (a) of this section, shall be paid by the owner or consignee and, in default of such payment, shall constitute a lien against any future importations made by such owner or consignee.

(C) 規則에 따라 算定되는 本條(a)項에서 定한 廢棄및 本條(b)項規定에 따라 許可된 標示의 變更이나 其他 行動에 關한 모든 費用(保健敎育厚生省官吏및 傭員의 旅費, 日當 또는 生活費와 給料를 包含) 및 本條(a)項規定에 따라 輸入을 拒否當한 物品에 對한 貯藏, 運搬, 勞務에 關한 모든 費用은 그 物品의 所有者 또는 荷受人이 支拂하여야 한다.

萬若 當該 所有者 또는 荷受人이 이를 支拂치 않을 때는 當該 所有者 또는 荷受人의 將來에 있을 輸入을 許可해서는 아니된다.

[*Regulations*] §*1.315 Definitions.* For the purposes of the regulations prescribed under section 801 (a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act;

〔規則〕 §1.315 定義. 聯邦食品藥品化粧品法 第801條(a) (b), (c)에서 定한 規則의 目的을 위하여 다음과 같이 定義를 定한다.

(a) The term "owner" or "consignee" means the person who has the rights of a consignee under the provisions of sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U.S.C. 1483, 1484, 1485).

(a) 〔所有者〕 또는 〔荷受人〕이란 1930年 關稅法(美合衆國法第19號, 1483, 1484, 1485改正)의 第483條, 第484號, 第485號로 定한 荷受人의 權利를 갖인 사람을 말한다.

(b) The term "chief of district" means the chief of the district of the Food and Drug Administration having jurisdiction over the port of entry through which an article is imported or offered for import, or such officer of the district as he may designate to act in his behalf in administering and enforcing the provisions of section 801 (a), (b), and (c).

(b) 〔地區의 長〕이란 物品을 輸入하거나 輸入用으로 供與할 輸入港에서 管轄權을 갖인 食品藥品局 地區事務所長또는 그 地區事務所長이 第801條(a) (b) (c)項을 代行할것을 命令한 官吏를 말한다.

§1.316 Notice of sampling. When a sample of an article offered for import has been re-

§1.316 見本採取(샘프링)의 通告.

地區의 長이 輸入用으로 供與될 物品의 見本을 要求하였을 때는 當該 物品을 管轄하는 稅關의 徵稅官

quested by the chief of district, the collector of customs having jurisdiction over the article shall give to the owner or consignee pormpt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the chief of district or the collector of customs of the results of examination of the sample.

은 即時 所有者 또는 荷受人에게 見本을 引渡하거나 引渡할 意思를 表明하도록 通告하여야한다.

所有者 또는 荷受人은 通告를 받았을 때는 當該物品을 保持하고 地區의 長 또는 稅關의 徵稅官으로부터 見本의 檢査結果에 對해서 通告를 받을 때까지는 物品을 配付해서는 아니된다.

§1.317 Payment for samples. The Food and Drug Administration will pay for all import samples which are found to be in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. Billing for reimbursement should be made by the owner or consignee to the Food and Drug Administration district headquarters in whose territory the shipment was offered for import. Payment for samples will not be made if the article is found to be in violation of the act, even though subsequently brought into compliance under the terms of an authorization to bring the article into compliance or rendered not a food, drug, device, or cosmetic as set forth in §1.319.

§1,317 샘풀에 對한 支拂

食品藥品局에서는 美聯邦食品藥品化粧品法에 適合함이 判明된 모-든 輸入샘풀의 價格에 對해서 支拂行爲를 하도록되어있다. 所有者 또는 荷受人은 貨物이 輸入되는 港口를 管轄하는 食品藥品局地區事務所에 對하여 支拂請求書를 提出하도록되어 있다. 샘풀에 對한 價格支拂은 萬若 當該物品이 法律에 違反되고 있음이 判明되었을 때는 아무리 그것이 許可되여서 손을 대므로해서 法律에 適合토록되거나 §1,319에서 定한바에 따라 食品, 藥品, 器具 및 化粧品以外의 것으로 轉用할 경우도 이를 行하지 아니 한다.

§1.318 Hearing. (a) If it appears that the article may be subject to refusal of admission, the chief of district shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall

§1,318 聽聞

(a) 萬若 物品이 輸入拒否되어야할 때에는 地區의 長은 所有者 또는 荷受人에게 理由를 드러서 輸入을 拒否하는 趣旨를 文書로서 通知하여야 한다.

그 通知에는 所有者 또는 荷受人이 反論을 펼 機會를 갖일만한 場所와 時間을 記載하여야한다. 適當

have an opportunity to introduce testimony. Upon timely request, giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article, and may be introduced orally or in writing.

한 時期에 適當한 理由를 들어서 申請하면 이 場所와 時期는 變更하여도 無妨하다. 이 反論은 該當 物品의 輸入 可否에 對해서만 限定시켜야하며 口頭 또는 文書로서 行할 수가 있다.

(b) If such owner or consignee submits or indicates his intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. if such application is not submitted at or prior to the hearing, the chief of district shall specify a time limit reasonable in the light of the circumstances, for filing such application

(b) 萬若 當該 所有者 또는 荷受人이 標示의 變更 또는 當該 物品을 法에 適合되도록 만들기 위해서 손질을 하거나 食品, 藥品, 用具, 化粧品 以外의 것으로 轉用시킬 許可를 申請하거나 그러한 意思를 表明하였을 때에는 證言은 이같은 申請을 支持하는 證據를 包含하고 있어야한다.

萬若 이러한 申請이 公聽會에서나 公聽會에 앞서서 提出되지않았을 때는 地區의 長은 狀況에 비추어서 適當한 理由가 있을 時期에 限하여 提出時期를 指示해 주어야 한다.

§*1.319 Application for authorization.* Application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug device, or cosmetic may be filed only by the owner or consignee, and shall

§ 1,319 許可申請. 標示의 變更이나 物品을 法에 適合시키고저 딴 行爲를 遂行하거나 食品, 藥品, 用具, 化粧品以外의 것으로 轉用하고자 할때는 所有者 또는 荷受人만이 이 申請을 行할 수가 있으며 다음 事項을 包含시켜야 한다.

(a) Contain detailed proposals for bringing the article into compliance with the act or rendering it other than a food, drug, devise, or cosmetic.

(a) 法에 適合시키기爲한 또는 食品, 藥品, 用具, 化粧品을 그들 以外의것으로 轉用시키는 詳細한 方法.

(b) Specify the time and place where such operations will be

(b) 이러한 作業을 하는 時期와 場所 및 그 作業完了에 要하는 大体的인 時間 明示.

carried out and the approximate time for their completion.

§1.320 Granting of authorization. (a) When authorization contemplated by S. 1. 319 is granted, the chief of district shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of an officer of the Food and Drug Administration or the Bureau of Customs, as the case may be;

(4) A time limit, reasonable in the light of the circumstances, for completion of the operations; and

(5) Such other conditions as are necessary to maintain adequate supervision and control over the article.

(b) Upon receipt of a written request for extension of time to complete such operation, containing reasonable grounds therefor, the chief of district may grant such additional time as he deems necessary.

(c) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the chief of district.

(d) If ownership of an article covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond and obtained a new authorization.

§1,320 許可의 承認

(a) §1,319에 對한 許可를 承認할 때는 地區의 長은 申請者에 對하여 文書로서 다음과 같은 內容을 明記해서 通告하여야 한다.

(1) 앞으로 밟어야할 手續節次.

(2) 拒否된 物品이나 그 物品의 一部에 對한 處置.

(3) 作業은 食品藥品局 또는 關稅局官吏의 監視下에서 行할것.

(4) 狀況에 비추어서 妥當하다는 作業終了 期限.

(5) 物品의 監視와 取締를 維持함에 必要한 其他 條件.

(b) 作業終了期限의 延長에 關한 文書에 따른 出願(妥當한 理由를 包含)을 接受하였을 때는 地區의 長은 必要하다고 認定되는 期間의 延長을 承認하여 줄 수가 있다.

(c) 許可는 妥當한 理由를 밝이고 地區의 長에게 申請이 있거든 變更시킬수 있다.

(d) 萬若 許可된 作業이 完了하기 前에 그 許可에 關係되는 物品의 所有權이 移動할 때는 새로운 所有者가 擔保를 設定하고 새로히 許可를 얻지않는 限, 當初 所有者에게 責任이 있다.

本條規定에 의거 承認된 許可는 該當 物品에 關하

Any authorization granted under this section shall supersede and nullify any previously granted authorization with respect to the article.

여 以前에 承認된 許可를 廢棄하거나 無效로 한다.

§1.321 Bonds. (a) The bonds required under section 801 (b) of the act may be executed by the owner or consignee on the appropriate form of a customs single-entry or term bond, containing a condition for the redelivery of the merchandise or any part thereof upon demand of the collector of customs and containing a provision for the performance of conditions as may legally be imposed for the relabeling or other action necessary to bring the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic, in such manner as is prescribed for such bond in the customs regulations in force on the date of request for authorization. The bond shall be filed with the collector of customs.

§ 1,321 擔保.

(a) 本法第801條 (b)項規定에서 定하는 擔保는 所有者 또는 荷受人이 商品이나 그 部分이 稅關의 徵稅官要求에 따라 再配付할 뜻의 條件을 包含하여 稅關의 通關手續이나 期限附擔保의 適正한 方式으로 設定하여야 한다. 또 이는 處置許可를 申請하였을 때에 施行되고있는 稅關規則에 記述되어 있는 方法으로 法的으로 課해진 標示의 變更이나 法에 適合시키기위한 其他 處置나 食品, 藥品, 用具 및 化粧品以外에의 轉用等의 條件遂行에 關한 條項을 包含시켜야 한다. 擔保는 稅關徵稅官에 對하여 提出할것.

(b) The collector of customs may cancel the liability for liquidated damages incurred under the abovementioned provisions of such a bond, if he receives an application for relief therefrom, upon the payment of a lesser amount or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances, but the collector shall not act under this regulation in any case unless the chief of district is in full agreement with the action.

(b) 稅關徵稅官은 (보다 小額의 費用을 支拂하고 法律과 狀況에 비추어서 適當하다고 看做되는 條件을 提示하고 救濟申請을 接受했을 때) 擔保에 對하여 앞서 記述한 諸 條件에 따라 惹起된 損失을 淸算하고자 債務를 取消할 수가 있다.

但 徵稅官은 如何한 境遇라 할지라도 그 行動에 있어 地區의 長의 完全한 同意없이는 이 規則에 의한 行動을 取해서는 아니된다.

§1.322 Costs chargeable in connection with relabeling and reconditioning inadmissible imports. The cost of supervising the relabeling or other action in connection with an import of food, drugs, devices, or cosmetics which fails to comply with the Federal Food, Drug, and Cosmetic Act shall be paid by the owner or consignee who files an application requesting such action and excutes a bond, persuant to section 801 (b) of the act, as amended. The cost of such supervision shall include, but not be restricted to, the following:

§1,322 輸入을 許容할 수 없는 物品에 對한 標示의 變更과 其他 處置에 關한 費用.

食品藥品化粧品法에 適合치못한 食品, 藥品, 器具 및 化粧品에 對하여 標示의 變更이나 其他 處置를 監視하는 費用은 이와같이 再標示 또는 處置를 申請하고 第801條(b)項規定에 의한 擔保를 設定한 所有者 또는 荷受人이 支拂하여야 한다. 이같은 監視費用은 다음과같은 것을 包含하여야 한다. (但 이것에만 限定시키는 것은 아니다.)

(a) Travel expenses of the supervising officer.

(a) 監視를 擔當할 官吏의 旅費.

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law.

(b) 監視를 擔當할 官吏가 勤務地에서 離脫할 때는 法으로 定해진 日當.

(c) Services of the supervising officer, to be calculated at a flat rate of $6.20 per hour(which shall include administrative expense), except that such services performed by a customs officer and subject to the provisions of section 5 of the act of February 13, 1911, as amended (19 U.S.C. 267), shall be calculated as provided in that act.

(c) 監視를 擔當할 官吏의 職務에 對한 費用, 1時間當 6,20$의 比率로 支拂할것(이는 行政費를 包含). 但 이 業務가 稅關官吏에 의해서 擔當遂行되고 1911年 2月13日改正된 法律(19美合衆國法律267)의 第5條에 의한 것일 때는 이 法律에 따라서 計算된다.

(d) Services of analyst, to be calculated at a flat rate of $7.68 per hour (which shall include the use of the chemical laboratories and equipment of the Food and Drug Administration).

(d) 分析試驗을 擔當한 職員의 業務에 對한費用 이는 1時間當 7,68$의 比率로 支拂할것. (이는 食品藥品局化學試驗室과 設備使用에 對한 費用을 包含함).

(e) The minimum charge for services of supervising officer and of analysis shall be not less than the charge for 1 hour, and time after the first hour shall be com-

(e) 監視를 遂行할 官吏와 試驗을 擔當할 職員에 對한 費用의 最低線은 1時間以上일것. 1時間超過分은 30分以下는 짜르고 1時間單位로할것.

puted in multiples of 1 hour, disregarding fractional parts less than 1/2 hour.

(d) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act.

(d) 輸出을 目的으로하는 食品, 藥品, 器具 및 化粧品은 다음의 境遇에는 本法의 不良品이라든가 不正標示라고는 看做하지 않는다.

(1) 外國購入者의 指示에 따르고 있을때.

(2) 輸出先國家의 法律에 違反되지 않을 때.

(3) 輸出用이라는 趣旨를 出荷包裝外側에 標示하고 있을 때.

然而나 萬若 이같은 物品이 國內市場에서 販賣되거나 國內去來에 供與될 때는 本法의 適用에서 免除될수 없게 된다.

CHAPTER IX - MISCELLANEOUS

第九章 雜 則

Separability Clause

Sec. 901 [391]. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

別節

第901條〔391〕

萬若 本法의 어느 條項이 憲法違反이라고 宣告되었을 때라든가 本法의 어떤 條項의 適用이 사람이나 狀況에 대하여 無效로 되었을 때는 法律의 딴 條項의 合憲性과 條項의 適用이 딴 사람이나 狀況에 對한 有效性은 그에 따라서 影響을 받지 아니한다.

Effective Date and Repeals

Sec. 902 [392]. (a) This Act shall take effect twelve months after the date of its enactment.

The Federal Food and Drugs Act of June 30, 1906, as amended (U.S.C., 1934 ed., title 21, secs. 1-15), shall remain in force until such effective date and except as otherwise provided in this subsection, is hereby repealed effective upon such date: Provided, That the provisions of section 701 shall become effective on the enactment of this Act, and thereafter the Secretary [of Agriculture] is authorized hereby to (1) conduct hearings and to promulgate regulations which shall be come effective on or after the effective date of this Act as the Secretary [of Agriculture] shall direct, and (2) designate prior to the effective date of this Act food having from having common or usual names and exempt such food from the requirements of clause (2) of section (403) (i) for a reasonable time to permit the for ulation, promulgation, and effective application of definitions and standards of identity therefore as provided by section 401: Provided further, That sections 502(j), 505, and 601(a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section (601(a) relates, such cosmetic shall not, actment, be deemed adulterated by reason of the prior to the ninetieth day after such date of enfailure of its label to bear the legend prescribed in such proviso: Provided further, That the Act of March 4, 1923 (U.S.C., 1946 ed., title 21, sec. 321a; 32 Stat. 1500, ch. 268), defining but-

発効日字와 廢止

第902條〔392〕

(a) 이 法律은 制定한 日字로부터 12個月 後에 發效한다.

1906年 6 月30日의 美聯邦食品藥品化粧品法(美合衆國法律1934ed年度版 法律第21號, 第 1 ~15條改正을包含)은 이 法律의 發效日까지 有效하다. 그리고 本條에서 定한 境遇를 除外하고 發效日에 廢止된다.

但 第701條는 이 法律發效日에 有效로 된다. 그리하여 其後 農務長官은 다음 事項에 對한 權限을 갖는다.

(1) 公聽會를 開催하고 이 法律發效日이나 農務長官이 定하는 其後日에 有效로 될 規則을 公布하는 일.

(2) 本法 發效日 以前에 通常名稱을 갖는 食品을 指定하고 第401條에서 定한 定義와 規格의 作成, 公布 및 有效한 適用을 許可함에 妥當한 期間에 對하여 第403條(i)項(2)節 基準適用을 除外할것. 또 이 法律第502條(j)項, 第505條와 第601條(a)項과 이를 各 條項施行에 關한 關係있는 모든 條項은 이 法律發效日에 有效하게 된다. 但 第601條(a)項에 關한 化粧品의 경우에는 그 條項에서 規定한 標示가 없드라도 發效日부터 90日間은 不良品이라고 看做되지 않는다.

더욱 버터의 定義와 基準을 定한 1923年 3 月 4 日의 法律(美合衆國法律1946年度版第21號, 第321(a)32法律 1500號, 第268章 및 包裝肉을 規定한 1919年 7 月 24日의 法律(美合衆國法律, 1946年度版第21號, 第321條(b)項, 41法律, 271, 第26章)및 1935年 8 月27日, 食藥品化粧品法 改正(美合衆國法律 1946年度版 第21號,

ter and providing a standard therefore; the Act of July 24, 1919 (U.S.C., 1946 ed., title 21, sec. 321b; 41 Stat. 271, ch. 26), defining wrapped meats as in package form; and the amendment to the Food and Drugs Act, section 10A, approved August 27, 1935. (U.S.C., 1946 ed., title 21, sec. 372a [49 Stat. 871, ch. 739]), shall remain n force and effect and be applicable to the provisions of this Act.

第372條 (a)項外〔49法律第871條, 739章〕) 은 繼續 有效하며 이 法律의 各 條 項에 對해서 適用된다.

(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended (U.S.C., 1946 ed., title 21, secs. 71-96; 34 Stat. 12600 et seq.).

[Sec. 7. Public Law 85-929 (21 U.S.C. 451 note): Nothing in this Act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended and extended (21 U.S.C. 71 and the following).]

‡ (c) Nothing contained in this Act shall be construed as in any way affecting, modifying repealing, or superseding the provisions of the virus, serum, and toxin Act of July 1, 1902 [now incorporated in Public Health Service Act of July 1, 1944, U.S.C., 1946 ed., title 42, ch. 6A, sec. 262]; the Filled Cheese Act of June 6, 1896 (U.S.C., 1946 ed., title 26, ch. 17, secs. 2350-2362); the Filled Milk Act of March 4, 1923 (U.S.C., 1946 ed., title 21, ch. 3, secs. 61-64); or the Import Milk Act of February 15, 1927 (U.S.C.,

(b) 食肉과 食肉製品은 1907年 3 月 4 日의 食肉檢査法 (美合衆國法律, 1946 年度版第21號第71~96條, 34法律 1260年度版 seg에 따른 改正을 包含함)의 通用에 關해서는 이 法律의 適用에서 除外된다.

〔公法 85-927 第 7 條 (美合衆國法律 451 : 이 法律의 어떤 部分도 家禽製品檢査法 (21 美合衆國法律第451號) 또는 1907年 3 月 4 日의 34法律 1260 (21 美合衆國法律第71號에 의한 改正을 包含함)의 食肉檢査法에서 定한 基準에 對해서 어떠한 食肉이나 食肉製品 또는 사람을 除外하는 것으로 解釋해서는 아니된

(c) 이 法律의 어떤 部分도 다음 各 法律을 어떤 方法으로도 影響받거나, 修正, 廢止, 代行하는 것으로 解釋해서는 아니된다.

(1) 1902年 7 月 1 日의 바이러스, 血淸과 독신法 〔現在 1944年 7 月 1 日, 美合衆國法律1946年度版 第42號 公衆保健廳法第262條에 合同되어있다〕

(2) 1896年 8 月 6 日의 필드치즈法 (美合衆國法律 1964年度版第26號, 第17章, 2350~2362條) 1923年 3 月 4 日의 필드밀크法 (美合衆國法律 1946年度版第21號,

1946 ed., title 21, ch. 4, secs. 141-149). (Approved June 25, 1938.)

第3章, 第61－64條)

(3) 1927年2月15日의 輸入밀크法(美合衆國法律 1946年度版 第21號, 第4章, 第141～149條)

(1938年6月25日承認)