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①

June 17, 2002

Daniel E. Troy, Esquire (GCF-1)
Chief Counsel
Food and Drug Administration
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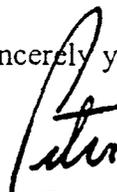
Dear Dan:

Enclosed is a copy of the Petition for Reconsideration and Stay of Action relating to two provisions in the FDA export regulations, about which I talked to you by telephone a few days ago.

The effective date for these regulations is June 19, 2002. Accordingly, I am requesting your prompt consideration of the request for a stay of the two specific provisions that are identified in this petition.

With best regards,

Sincerely yours,



Peter Barton Hutt

Enclosure

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June 17, 2002

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

Re: Petition for Reconsideration and Stay of Action
Docket No. 98N-0583

The Grocery Manufacturers of America (GMA) and the Cosmetic, Toiletry, and Fragrance Association (CTFA) submit this petition in accordance with 21 C.F.R. 10.33(b) and 10.35(b) for reconsideration and stay of two provisions in the regulations promulgated by the Commissioner of Food and Drugs in Docket No. 98N-0583 (notification and recordkeeping requirements relating to export of food and cosmetics).

A. Decision Involved

FDA published proposed regulations to establish notification and recordkeeping requirements for export of products that may not be marketed or sold in the United States in 64 Fed. Reg. 15944 (April 2, 1999) and promulgated final regulations in 66 Fed. Reg. 65429 (December 19, 2001). The effective date for these regulations was extended until June 19, 2002, in 67 Fed. Reg. 34387 (May 4, 2002).

This petition for reconsideration and stay is directed only to the portion of these regulations that relate to the application to exported food and cosmetic products of Section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and only to two provisions in those regulations: (1) the last sentence in Section 1.101(b), which states that export records for a food or cosmetic shall be made available to FDA upon request during an inspection for review and copying, and (2) Section 1.101(b)(2), which places the burden on a food or cosmetic company to prepare a notarized certification by a responsible company official that an exported product does not conflict with the laws of the importing country.

B. Action Requested

Petitioners request the Commissioner to reconsider and to revoke the last sentence in Section 1.101(b) and to revoke Section 1.101(b)(2). Petitioners also request that these two provisions be stayed during this reconsideration.

Dockets Management Branch (HFA-305)
June 17, 2002
Page 2

C. Statement of Grounds

This petition addresses two separate and different provisions of the export regulations. Each of these provisions is described separately below and discussed in detail in the attached two appendices.

1. Records Inspection

For a full fifty years, FDA has taken the consistent position that the FD&C Act does not authorize the Agency to require a food or cosmetic company to disclose records to the Agency relating to these products. Congress has authorized records inspection for a limited category of products (prescription drugs, restricted medical devices, infant formula, and nonprescription drugs) but has repeatedly declined to extend records inspection authority to cover food generally or cosmetics.

FDA acknowledged this lack of authority in a press release issued by the Agency at the time of the enactment of the inspection provisions in Section 704 of the Act in 1953. FDA officials have repeatedly testified before Congress that the Agency lacks records inspection authority for food and cosmetics from 1962 to the present. None of this history is discussed in the preamble to the proposed or final regulations, and these preambles provide no explanation for the present assertion of this authority. A full discussion of all of these points is set forth in Appendix A to this petition.

Accordingly, petitioners request that the last sentence of the first paragraph in Section 1.101(b) of the export regulations, as promulgated in 66 Fed. Reg. 65429, 65447 (December 19, 2001), be revoked.

2. Compliance With Foreign Law

Under the export provision in the Federal Food and Drugs Act of 1906, which required compliance with foreign law, FDA promulgated implementing regulations that explicitly acknowledged that FDA, rather than the regulated industry, had the burden of proving lack of compliance with foreign law. The courts interpreted the export provision in the 1906 Act in the same way.

The export provision in the legislation that ultimately became Section 801(e)(1)(B) of the FD&C Act was initially drafted by FDA to reverse the burden of proof, and thus to require the regulated industry to demonstrate compliance with foreign law. When this was brought to the attention of Congress, the pending legislation was changed in 1937 specifically to retain the burden of proof on FDA. The legislative history demonstrates that Congress intended the export provision under the 1938 Act to remain the same as the export provision under the 1906 Act. None of this legislative history is discussed in the preamble to the proposed or final regulations. A full discussion of all of these points is set forth in Appendix B to this petition.

Dockets Management Branch (HFA-305)
June 17, 2002
Page 3

In addition to the illegality of Section 1.101(b)(2) of the export regulations, this provision would have serious practical and economic impacts on food and cosmetic companies. It is common practice for companies who export products to label them in the United States in foreign languages, before export, in order to meet foreign requirements throughout the world. For sixty-four years they have done this under Section 801(e)(1)(B) of the FD&C Act without the need for special documentation of the type that would now be required under Section 1.101(b)(2). The new provision would require the preparation of tens of thousands of affidavits just for shipping products to our neighbors in Mexico (Spanish labeling) and Canada (dual French and English labeling), and new affidavits would be required for every product variation and every label change. FDA has presented no evidence that the approach used for the last sixty-four years has in any significant way harmed foreign consumers or relations between the United States and our trading partners.

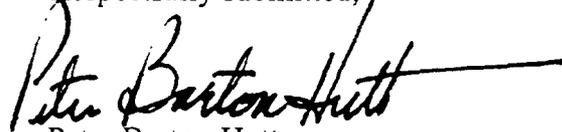
Accordingly, petitioners request that Section 1.101(b)(2), as promulgated in 66 Fed. Reg. 65429, 65447 (December 19, 2001), be revoked.

3. Timeliness of Petition

Sections 10.33(b) and 10.35(b) of the FDA procedural regulations state that a petition for administrative reconsideration or for stay of action is ordinarily to be filed within thirty days after the date that a regulation is published in the Federal Register. Both provisions state, however, that a petition may be accepted by the Commissioner at a later date for good cause.

In this matter, the petitioners did not recognize the significance of the two provisions that are the subject of this petition until the effective date of the regulations drew near. Following the extension of the effective date, petitioners concluded that it would be appropriate to submit this petition for a further stay of action in order to provide time for reconsideration of these two matters. Because of the importance of these matters, petitioners request the Commissioner to exercise the discretion set forth in the applicable regulations to reconsider these matters and to stay their effective date until that reconsideration can be completed.

Respectfully submitted,



Peter Barton Hutt
Counsel for Petitioners

cc: Thomas J. Donegan, Jr., Esquire
James H. Skiles, Esquire

June 17, 2002

Appendix A

FDA Has No Authority Under the Federal Food, Drug, and Cosmetic Act to Require Manufacturers of Food and Cosmetics to Disclose to FDA Inspectors Company Records Relating to Exported Products

This Appendix demonstrates that FDA has no statutory authority to require Agency inspection of company records relating to compliance of exported food and cosmetics with Section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

I. THE RECORDS INSPECTION PROVISION OF THE REGULATION EXCEEDS FDA'S STATUTORY AUTHORITY.

A. Section 704 Of the FD&C Act Does Not Authorize FDA To Inspect The Records of Food and Cosmetic Manufacturers.

The inspection authority granted to FDA by the FD&C Act does not extend to the mandatory examination of records maintained by food and cosmetic manufacturers. Under Section 704(a), the Agency's authority to inspect the factory, warehouse, establishment, or vehicle of a food or cosmetic manufacturer is limited to "all pertinent equipment, finished and unfinished materials, containers, and labeling therein." In particular, this authority does *not* provide for the review of records. Indeed, each time Congress has determined that records inspection is warranted -- for prescription drugs,¹ restricted devices,² infant formula³, and nonprescription drugs⁴ -- it specifically amended Section 704(a) to provide FDA with this expanded inspection authority. If FDA already possessed the authority to inspect records under the FD&C Act, no amendment of the Act would have been required and the records inspection provisions relating to prescription drugs, restricted devices, infant formula, and nonprescription drugs, would be superfluous.

The Agency has sought records inspection authority for food and cosmetics establishments from Congress on several occasions. These efforts have been vigorously opposed by industry because of the serious legal and constitutional issues raised and because FDA has adequate enforcement powers without records inspection. Through the testimony of both the Agency and industry representatives, Congress has been able to consider the competing interests

¹ 76 Stat. 780 (1962).

² 90 Stat. 539 (1976).

³ 94 Stat. 1190 (1980).

⁴ 111 Stat. 2296 (1997).

involved, and has determined repeatedly that records inspection authority is not warranted for food and cosmetics products.

B. The Inspection Of Records Is Not Authorized Under Sections 701(a) and (b) Of the FD&C Act.

Section 701(a) of the FD&C Act provides that the Agency has the authority to promulgate regulations for the efficient enforcement of the FD&C Act generally and Section 701(b) grants this authority jointly to the Secretary of the Treasury and FDA with respect specifically to Section 801 of the FD&C Act. After 50 years of acknowledging its lack of authority under Section 704 to inspect the records of food and cosmetic manufacturers, FDA cannot now assert that it possesses this authority under Sections 701(a) and 701(b).⁵ Sections 701(a) and 701(b) only authorize FDA to issue regulations implementing other substantive provisions of the Act. They do not permit FDA to contravene congressional intent by imposing regulatory requirements exceeding the limited inspection authority provided under the statute.⁶ Therefore, Sections 701(a) and 701(b) only helps if another section of the Act authorizes FDA access to company records. None does.

For example, Congress has specifically provided, and the Agency has exercised, limited records inspection authority under Section 404 of the FD&C Act,⁷ and the food industry has not disputed this authority. Section 404 provides FDA with explicit emergency permit authority over food that "may, by reason of contamination with microorganisms... be injurious to health." Pursuant to Section 404, FDA has promulgated regulations to assure adequate processing of acidified and low acid canned food in order to prevent contamination with pathogens.⁸ These specialized provisions are warranted in light of the extreme toxicity of botulism, which could result from the improper processing of these products.

Under Section 404(c), Congress explicitly granted FDA the authority to inspect any food establishment "for the purpose of ascertaining whether or not the conditions of the permit are being complied with." This authority is in addition to the general inspection authority under Section 704, and thus was clearly intended by Congress to extend beyond the limited power provided to FDA for all other types of food inspection. In the context of this specific and broader statutory grant of authority to inspect for compliance with an emergency permit, it is reasonable to include those records that bear directly on such compliance. This broader records inspection authority under Section 404(c) is limited to emergency permits, however, and stands in stark contrast to the narrower inspection authority under Section 704(a). Section 404(c) has no bearing on FDA's authority to conduct records inspections in other circumstances.

⁵ Under no circumstances can these regulations be regarded as promulgated under Section 701(b), because they were not issued jointly by the Department of the Treasury and FDA as required under that provision.

⁶ *National Confectioners Association v. Califano*, 569 F. 2d 690, 695 (D.C. Cir. 1978).

⁷ 21 C.F.R. §§ 108.25(g), 108.35(h).

⁸ 21 C.F.R. Parts 113 and 114.

II. FDA HAS REPEATEDLY ACKNOWLEDGED THAT IT LACKS THE AUTHORITY TO INSPECT FOOD AND COSMETIC RECORDS.

Repeatedly throughout the history of the FD&C Act, FDA has acknowledged the limitations on its authority which prohibit the Agency from requiring food and cosmetic manufacturers to disclose their records during an inspection. In 1953, Congress enacted the present factory inspection provision of the FD&C Act -- Section 704(a) -- granting FDA its current inspection authority with respect to food and cosmetic manufacturers.⁹ Although FDA had sought statutory authority to inspect all pertinent records relating to food and cosmetic production, Congress withheld such authority from the Agency.

A press release issued by the Agency on August 27, 1953 (copy attached) explicitly acknowledged this lack of authority. The press release quoted the Commissioner of Food and Drugs as stating: "The legislative history indicates Congress did not intend to include prescription files, formula files, complaint files, and personnel files within the scope of required inspections. FDA interprets this to mean that inspection of these records will be on a voluntary basis." Thus, the Agency's contemporaneous interpretation of Section 704(a) acknowledged Congress's refusal to grant records inspection authority.

Since 1953, Congress has amended Section 704(a) to grant records inspection authority for prescription drugs, restricted devices, infant formula, and nonprescription drugs, but has continued to deny the Agency authority to inspect records relating to all regulated products generally or to food and cosmetics in particular. These amendments demonstrate that Congress was aware that the review of records is outside the scope of the general inspection authority provided under the Act.

FDA has gone before Congress several times since the original enactment of Section 704 seeking expanded inspection authority under the Act. In making these appeals, the Agency consistently has maintained that it lacks the statutory authority to inspect food and cosmetic records. After evaluating the arguments put forth by FDA and industry representatives, Congress has repeatedly determined that the requested authority is unnecessary and inappropriate.

Under well-settled principles of administrative law, the Agency's contemporaneous and longstanding interpretation of a provision of the FD&C is presumed correct.¹⁰ FDA bears a heavy burden to justify the reversal of its longstanding position, held

⁹ In 1952, the original version of Section 704 of the FD&C Act was struck down as unconstitutionally vague by the United States Supreme Court. *United States v. Cardiff*, 344 U.S. 174 (1952).

¹⁰ *E.g., Atchison, T.&S.F.R. Co. v. Wichita Bd. of Trade*, 412 U.S. 800, 807 (1973) (an agency's settled policy "embodies the agency's informed judgement that, by pursuing that course, it will carry out the policies committed to it by Congress... [and] that those policies will be carried out best if the settled rule is adhered to."); *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (weight given to rulings, interpretations and opinions of an agency depends upon "the (continued...)

since the enactment of section 704 in 1953, that it lacks records inspection authority for foods and cosmetics.¹¹ Rather than meeting this burden, FDA makes no attempt to explain its revised interpretation of the FD&C Act. Indeed, the preamble to the proposed and final regulation makes no reference to the Agency's repeated statements before Congress and others that FDA has no records inspection authority in the food and cosmetic areas.

The Agency's unjustified reversal of its longstanding position is particularly egregious in the instant case, where FDA has repeatedly told Congress that it lacks the authority to inspect food and cosmetic records. Over the past five decades, Congress has relied on this testimony in making its legislative determinations relating to the Agency. FDA cannot now usurp Congress's power by attempting to reinterpret the statute at this late date.

A. The 1962 Hearings Relating To The Drug Industry Act Of 1962.

In a hearing before the House Committee on Interstate and Foreign Commerce relating to the Drug Industry Act of 1962, Abraham Ribicoff, the Secretary of the Department of Health, Education, and Welfare, and George Larrick, the Commissioner of Food and Drugs, testified regarding the scope of the inspection authority provided under Section 704(a).¹² This testimony and the FDA's written statements unequivocally demonstrate the Agency's understanding that the general factory inspection provisions of Section 704(a) exclude access to records. An exchange between the Chairman of the Committee and Secretary Ribicoff illustrates this point:

thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade"); *Shapiro v. United States*, 335 U.S. 1, 12 (1948) (contemporaneous administrative interpretation of a statute is highly relevant and material evidence entitled to serious consideration).

¹¹ E.g., *Motor Vehicle Manufacturers Association v. State Farm Mutual Insurance*, 463 U.S. 29, 48-49 (1983) (when departing from a settled policy, an agency must explain both the basis for its decision and the basis for reversing its previous policy); *Local 777, * * * AFL-CIO v. National Labor Relations Board*, 603 F.2d 862 (D.C. Cir. 1979) (when... [an agency] announces no principled reason for such a reversal, its action is arbitrary and the courts should be quick to so declare."); *General Electric Co. v. Gilbert*, 429 U.S. 125, 142-43 (1976) (assigning little weight to an agency's statutory interpretation which "flatly contradict[ed]" the position previously articulated by the agency); *Madison Galleries, Ltd. v. United States*, 870 F.2d 627, 631 (Fed. Cir. 1989) ("an agency interpretation which conflicts with the same agency's earlier interpretation is entitled to considerably less deference than a consistently held agency view"), citing *INS v. Cardoza-Fonseca*, 480 U.S. 421, 447 n. 30 (1987); *Seldovia Native Assoc., Inc. v. Lujan*, 904 F.2d 1335 (9th Cir. 1990) ("when an agency reverses a prior policy or statutory interpretation, its most recent expression is accorded less deference than is ordinarily extended to agency determinations").

¹² "Drug Industry Act of 1962," *Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives*, 87th Cong., 2nd Sess. 60, 67-74 (1962).

The CHAIRMAN: ... In your statement, you say that you are required to establish and police safe tolerances for known poisons in our food supply.

You are required to approve new drugs and to certify antibiotics from the standpoint of safety and to some extent efficacy. That is under present law?

SECRETARY RIBICOFF: Yes.

The CHAIRMAN: In those fields, are you authorized to look at the complaint files?

SECRETARY RIBICOFF: We are not.

The CHAIRMAN: Are you authorized to look at the shipping records?

SECRETARY RIBICOFF: No sir.

The CHAIRMAN: Are you authorized to look at the formula files?

SECRETARY RIBICOFF: We are not.

The CHAIRMAN: Are you doing a good job in those fields, from your viewpoint?

SECRETARY RIBICOFF: I would say that we cannot do a good job with these restrictions.¹³

Shortly after this exchange, Commissioner Larrick added: "We can do a much more satisfactory job and a more efficient job in these areas that you refer to Mr. Chairman, if we do have the authority that we seek in this amendment."¹⁴ The Commissioner went on to admit that "in spite of the limitation of the statute, the great bulk of American industry deals with us forthrightly and does not hesitate to give us [the] information [we need]" on a voluntary basis.¹⁵ Ultimately, the expanded inspection authority sought by the Agency at that time was granted by Congress only with respect to prescription drugs.

¹³ *Id.* at 72.

¹⁴ *Id.*

¹⁵ *Id.* at 73.

B. The 1971 Hearings Relating To FDA Oversight/Food Inspection

In 1971, the Agency again sought expansion of its existing food inspection authority from Congress. In hearings before the Subcommittee on Public Health and Environment of the House Committee on Interstate and Foreign Commerce, Charles Edwards, the Commissioner of Food and Drugs, and Virgil Wodicka, the Director of the FDA Bureau of Foods, argued that the Agency's efforts to monitor the quality control systems of food manufacturers were hampered because the Agency lacked the authority to inspect records.¹⁶ In his testimony, Dr. Wodicka explicitly acknowledged that Congress had repeatedly withheld the authority to inspect food records from the Agency:

DR. WODICKA: Our inspection efforts have been almost entirely concentrated on the inspection of the plant and the operations in it, and have paid somewhat less attention to the controls of those operations exercised by the company.

This is in part because the agency has a number of times asked for authority to require the companies to show quality control records and the Congress has never felt that this was a necessary authority.

As a consequence, we are able to look at these records only from those companies that will voluntarily show them.

I think the number of such companies is increasing, and we want to mount a training program to put our inspectors in a position to make more effective use of this kind of information when it is available.

MR. ROGERS: In other words, you are saying that the law presently is deficient in the authority you have to look at records for quality control?

DR. WODICKA: Yes, sir.¹⁷

C. The 1978 Hearings Relating To The Food Safety And Nutrition Amendments Of 1978

Seven years later, FDA again told Congress that it lacked records inspection authority for foods. In 1978, hearings were held before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce with respect to the

¹⁶ "FDA Oversight - - Food Inspection," *Hearings Before the Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce, House of Representatives, 92nd Cong., 1st Sess. 130-131 (1971).*

¹⁷ *Id.* at 130.

Food Safety and Nutrition Amendments of 1978.¹⁸ On numerous occasions during these hearings, FDA officials specifically commented on the Agency's lack of authority to review records during its inspections of food establishments.

1. Comments of the Department of Health, Education, and Welfare

Julius Richmond, the Assistant Secretary for Health, submitted comments reflecting "the general policy views of the Department" as an appendix to his prepared statement before the Subcommittee.¹⁹ The comments referenced the limitations on the Agency's inspection authority several times, arguing that "[E]nforcement of the current law with respect to food is hampered by the limitations on FDA's authority and by the absence of provisions that would make it easier for the Agency to become aware of, and pursue violations of law."²⁰ The comments argued that a more expansive inspection authority was necessary for the efficient enforcement of the Act:

FDA's ability to enforce the food laws is most hampered by the Agency's relatively narrow inspection authority. Enforcement of the food laws is made difficult because FDA is not able to insist on access to manufacturer's records. The lack of access to records inhibits enforcement because some violations of the law, for example, those related to the use of ingredients, can only be discovered by reviewing records. In other cases, proof of violations would be simplified if records could be reviewed. FDA's inspection authority should be expanded to provide for access to records bearing on whether a food is adulterated or misbranded as found in H.R. 10358 (Rogers).²¹

Despite specific consideration of these concerns, however, Congress refused to extend the Agency's inspection authority to include access to food records. Having failed repeatedly in its efforts to obtain records inspection authority through legislation, FDA cannot now accomplish by regulation that which Congress has specifically denied by statute.

¹⁸ "Food Safety and Nutrition Amendments of 1978," *Hearings Before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, House of Representatives*, 95th Cong., 2nd Sess. (1978).

¹⁹ *Id.* at 119-131.

²⁰ *Id.* at 125.

²¹ *Id.* at 128-129.

2. Statement of the FDA Chief Counsel

FDA's Chief Counsel, Richard Cooper, also focussed on the Agency's lack of records inspection authority in his statement before the Subcommittee. Referencing the Agency's limited enforcement authority, Mr. Cooper testified:

Finally, to assist in the discovery of violations, H.R. 10358 would expand FDA's inspection authority.

. . . I believe it is quite important that the Food and Drug Administration be able to inspect the records that bear on possible adulteration or misbranding, that bear on ingredients that go into food, so that we can determine from the records where we cannot always determine from laboratory analysis what ingredients were put into the food, whether unapproved food additives are being used, and the like.²²

Mr. Cooper's prepared statement to the Subcommittee emphasized the restrictions on FDA's inspection authority under the Act:

Under current law, food processors are not required to permit FDA to inspect food processing records that may bear on whether products are adulterated or misbranded. FDA's ability to enforce the law is impaired by this limitation on its inspection authority because some violations of law (*e.g.*, those related to the use of ingredients) can be discovered most efficiently by reviewing records.²³

Nonetheless, Congress did not grant the expanded inspection authority requested by FDA.

D. The 1978-1979 Hearings Relating To The Drug Regulation Reform Act of 1978/1979

In hearings before the House of Representatives and the Senate in 1978 and 1979 relating to the Drug Regulation Reform Act, FDA continued to seek expanded factory inspection authority under Section 704(a). FDA Commissioner Donald Kennedy sought increased inspection authority with respect to nonprescription drugs,²⁴ for which Section 704(a) at that time

²² Id. at 310.

²³ Id. at 315-316.

²⁴ *E.g.*, "Drug Regulation Reform Act of 1979," *Hearings Before the Subcommittee on Health and Scientific Research of the Committee on Labor and Human Resources, United States Senate*, 96th Cong., 1st Sess. 361 (1979) ("We think enforcement provisions of the law should be made fairer and more effective by . . . expanding FDA's inspection authority, . . . so that FDA can better develop the facts needed to prove criminal and other violations when they occur."); (continued...)

provided the identical authority as food and cosmetics. In their testimony, FDA representatives adhered to the Agency's longstanding position that the general inspection authority of Section 704(a) does not extend to records inspection. They acknowledged that records inspection is authorized only where Congress has specifically granted FDA broadened authority, as with prescription drugs.

In his prepared statement to the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, Richard Cooper, FDA's Chief Counsel, noted that "under current law, FDA may inspect records relating to the manufacture of prescription drugs, but not records relating to over-the-counter drugs."²⁵ Testifying before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, the Secretary of Health, Education, and Welfare, Joseph Califano, explained that the proposed legislation "adds additional enforcement tools to present law."²⁶ Specifically, the Secretary explained that "the bill extends the factory inspection authority of the present act, which now permits inspection of records of prescription drug manufacturers, to reach records of nonprescription (OTC) drug manufacturers as well."²⁷

E. The 1991 Hearings on the Food, Drug, Cosmetic, and Device Enforcement Amendments

Testimony by FDA officials, including FDA Commissioner Kessler, in 1991 reflects the Agency's continued recognition that it does not possess the statutory authority to require food manufacturers to disclose their records. In testimony before the Senate Committee on Labor and Human Resources in 1991, Commissioner Kessler stated that Congress and the Agency "need to look at enhancing our inspection authority, including records inspection."²⁸ Expanding on this point, Commissioner Kessler later stated:

I have yet to see an agency get additional enforcement tools without assurances on the other hand. And I recognize that. But it's very hard, for example, to track down the maker of bogus apple juice or track down when oranges don't go into a factory but

"Drug Regulation Reform Act of 1978, Part 2," *Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives, 95th Cong., 2nd Sess.* 1405 (1978) ("Our inspection authority would also be expanded so that we could reach records relating to possible violations involving over-the-counter drugs.").

²⁵ "Drug Regulation Reform Act of 1978, Part 2," note 24 *supra*, at 1414.

²⁶ "Drug Regulation Reform Act of 1978," *Hearings Before the Subcommittee on Health and Scientific Research of the Committee on Human Resources, United States Senate, 95th Cong., 2nd Sess.* 244 (1978).

²⁷ *Id.*

²⁸ "Role of Commissioner of Food and Drugs," *Hearing Before the Committee on Labor and Human Resources, United States Senate, 102nd Cong., 1st Sess.* 10 (1991).

orange juice comes out at night and you can't go and inspect records, it really ties the hands of the field.²⁹

In a hearing before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, Commissioner Kessler also explicitly acknowledged FDA's lack of records inspection authority under the Act. The bill under consideration would have amended Section 704(a) to broaden FDA's general inspection authority to include, among other things, the inspection of records.³⁰ Referencing a report by the Edwards Committee citing FDA's existing enforcement authorities, Congressman Dingell asked the Commissioner:

Going down, with regard to foods, it says you have inspection authorities; you have none with regard to containers, commercial testing laboratories, photographs during inspection, record inspection, record copying. . . . Is that not so?³¹

Commissioner Kessler agreed with this characterization of the Agency's food inspection authority, replying: "It certainly creates a serious problem."³²

During this testimony, Commissioner Kessler was quite candid regarding the absence of statutory authority to conduct records inspections for food. Commissioner Kessler explicitly recognized that "[T]his legislation would provide the ability to inspect records in the food area, as we have in other areas."³³

The 1991 legislation that would have expanded the Agency's inspection authority for foods and cosmetics was not passed by Congress. Thus, the Agency today remains as it has for over 40 years -- without records inspection authority for food and cosmetics.

F. The Food and Drug Administration Modernization Act of 1997

During Congressional consideration of the Food and Drug Administration Modernization Act of 1997 (FADAMA), the food, nonprescription drug, and cosmetic industries proposed that provisions be added to the legislation that would require national uniformity in the regulation of these product categories. FDA responded that it would object to such provisions unless the legislation also included records inspection. The nonprescription drug industry

²⁹ *Id.* at 21.

³⁰ "Food, Drug, Cosmetic, and Device Enforcement Amendments," *Hearing Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives*, 102nd Cong., 1st Sess. 13-14 (1991).

³¹ *Id.* at 77.

³² *Id.*

³³ *Id.* at 86.

accepted this trade-off, and FADAMA accordingly included both provisions.³⁴ The food industry abandoned its request for national uniformity rather than accept records inspection. The cosmetic industry continued its request for national uniformity without accepting records inspection and, after a lengthy Senate debate,³⁵ obtained a revised national uniformity provision.³⁶ Accordingly, FDA emerged from the most recent congressional consideration of this matter with another acknowledgement that it has no records inspection authority for food and cosmetics but no additional authority to inspect the records of food and cosmetic companies.

III. THE CASES CITED BY FDA IN SUPPORT OF PRIOR RECORDS INSPECTION PROPOSALS FAIL TO SUPPORT THE AGENCY'S RECENT ATTEMPT TO REINTERPRET THE STATUTE.

The preambles to the proposed and final regulations contain no legal analysis of the statutory authority on which FDA relies for inspection of food and cosmetic records. In a preamble to a prior proposed regulation, however, the Agency devoted substantial space to arguing that it possesses the legal authority to require the disclosure of food records.³⁷ In particular, the Agency contended that a few older court decisions support its new claim of authority. A review of these cases, however, demonstrates that they are not on point.

The Agency asserts that the 1973 Supreme Court decision in *Weinberger v. Bentex Pharmaceuticals, Inc.*³⁸ supports its contention that "FDA may require records to be maintained in specific instances and may inspect those required records, despite the act's lack of express, general statutory authority to inspect records."³⁹ In *Weinberger*, the Court reversed the lower court's holding that FDA lacked jurisdiction under the FD&C Act "to decide in an administrative proceeding what is a 'new drug' for which an NDA is required."⁴⁰ In the lower court's view, the judiciary had exclusive jurisdiction to make such determinations.⁴¹ In

³⁴ Sections 412(a) and (b) of FADAMA, 111 Stat. 2296, 2374 (1997).

³⁵ 143 Cong. Rec. S8837 ff. (September 5, 1997), S8878 ff. (September 8, 1997), S9133 ff. (September 22, 1997) (daily eds.).

³⁶ 143 Cong. Rec. S9145 ff. (September 11, 1997) (daily ed.). Section 412(d) of FADAMA, 111 Stat. 2296, 2376 (1997).

³⁷ 61 Fed. Reg. 3885 (February 2, 1996) (FDA records inspection of nutrient descriptor and disease claims for food). Notably, the preamble did not address FDA's repeated testimony to Congress regarding its lack of inspection authority for food industry records.

³⁸ 412 U.S. 645 (1973).

³⁹ 61 Fed. Reg. at 3888.

⁴⁰ 412 U.S. at 648.

⁴¹ The lower court had concluded that the Drug Amendments of 1962 to the FD&C Act established two distinct forums for the regulation of drugs -- an administrative forum and a judicial forum. In the lower court's view, the FDA's role was limited to premarketing clearances for new drugs or withdrawal of previous drug approvals, while the judiciary had exclusive (continued...)

concluding that it could “discern no such jurisdictional line under the Act,” the Supreme Court reasoned: “One function is not peculiar to judicial expertise, the other to administrative expertise. The two types of cases overlap and strongly suggest that Congress desired that the administrative agency make both kinds of determination.”⁴²

Weinberger thus rested on an analysis of congressional intent, and its finding of “implicit” authority under general principles governing the primary jurisdiction of administrative agencies has no application to the narrow issue of authority to inspect company records. After five decades of unsuccessful requests that Congress enact records inspection authority under the Act, no credible argument can be made that Congress has always intended the Agency’s inspection authority to reach food and cosmetic records. FDA’s reliance on *Weinberger* to claim legal authority to implement the proposed regulation thus is in error.

National Confectioners Association v. Califano,⁴³ also cited by the Agency, similarly rests on the court’s analysis of congressional intent. In *National Confectioners*, the United States Court of Appeals for the Tenth Circuit recognized that, as a legal matter, “the regulation must be consistent with Congressional intent and the substantive provisions of the whole statute.”⁴⁴ Although the Tenth Circuit made the factual determination that the particular source coding and recordkeeping requirements under consideration were permissible, there are several reasons why this holding cannot be used to justify mandatory records inspection.

First, and most important, *National Confectioners* applied only to the requirement that food manufacturers make and keep records. It had nothing to say about FDA’s authority to inspect those records. FDA did not assert that it could inspect food company records and the court did not so hold.⁴⁵

Second, *National Confectioners* was decided in January 1978. Later that year, FDA made several statements before Congress acknowledging its lack of food records inspection authority under the Act. Since this decision, the Agency has continued to seek congressional authorization for records inspection for more than two decades. If the Agency’s authority to inspect records was settled by *National Confectioners*, FDA surely would not have persisted in its testimony to Congress that its lack of records inspection authority in the food area hampers its

jurisdiction to enforce the requirement that new drugs be cleared as safe and effective before marketing. *Id.* at 648-649.

⁴² *Id.* at 652.

⁴³ 569 F.2d 690 (D.C. Cir. 1978).

⁴⁴ *Id.* at 695.

⁴⁵ Even if the court had found records inspection authority in *National Confectioners*, this finding would have no bearing in the instant case. The regulation at issue in *National Confectioners* related to distribution records, not food records generally. Section 703 of the FD&C Act explicitly authorizes the Agency “to have access to and to copy all records showing the movement [of food] in interstate commerce.” This statutory provision has no application to the records required to be presented for inspection under the export regulation.

enforcement efforts. Nor would Congress have continued to conduct hearings regarding the alleged need for such authority.

Third, *National Confectioners* explicitly rejects Section 701(a) as an independent source of authority not found elsewhere in the Act. Emphasizing the importance of congressional intent, the court stated: "Section 701(a) is not a license for expansion of the FDA's regulatory authority based on fanciful interpretations of the substantive portions of the Act."⁴⁶

Finally, an application of the legal standard articulated in *National Confectioners* mandates a determination that FDA lacks the authority to impose the records inspection requirements of the proposed regulation. As the Tenth Circuit emphasized, a regulation must be consistent with congressional intent. In light of the overwhelming evidence that Congress intended to withhold records inspection authority from FDA in the food area, and the Agency's repeated historical acknowledgements that such authority has not been granted, the assertion that FDA may require food manufacturers to disclose records under the proposed regulation cannot be sustained.

The Agency also cites *Toilet Goods Association v. Gardner*⁴⁷ to support its broad assertion that "FDA may impose recordkeeping requirements where they effectuate the act's goals."⁴⁸ In *Toilet Goods*, however, the Supreme Court did not reach the ultimate issue of whether the FDA regulation was an impermissible exercise of authority.⁴⁹ Rather, as every student of Administrative Law knows, the Court held that the Toilet Goods Association's challenge to the regulation was not ripe for judicial review.⁵⁰

⁴⁶ *Id.* at 695.

⁴⁷ 387 U.S. 158 (1967).

⁴⁸ 61 Fed. Reg. at 3888.

⁴⁹ The regulation, promulgated to implement the Color Additive Amendments of 1960, provided that FDA could suspend a certification for batches of color additives if a person refused to provide the Agency with free access to "all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived." 387 U.S. at 161.

⁵⁰ *Id.* at 160-161.

IV. CONGRESS'S REFUSAL TO GRANT RECORDS INSPECTION AUTHORITY TO FDA REFLECTS A REASONED DETERMINATION THAT SUCH AUTHORITY IS UNNECESSARY FOR THE EFFECTIVE ENFORCEMENT OF THE FD&C ACT.

A. Congress Has Determined That The Agency's Enforcement Authority Is Sufficiently Expansive Without Records Inspection Authority.

Congress's continued refusal to provide FDA with records inspection authority for food and cosmetics has been reasonable and principled. In response to the Agency's efforts to obtain such authority, the food and cosmetics industries have raised serious concerns regarding the disclosure of records during a warrantless FDA inspection.⁵¹ Indeed, granting FDA inspectors the authority to review company records without a search warrant and without a showing of probable cause to believe there has been a violation of law raises serious constitutional issues.

The constitutional issues raised by such unchecked executive authority are particularly grave in light of the criminal liability imposed on manufacturers under the FD&C Act. Any violations discovered during an inspection could be used by the Agency in a prosecution under the FD&C Act's "strict liability" criminal standard. The Supreme Court has held on two occasions that an individual is subject to criminal sanctions, including imprisonment, for any violation of the Act, regardless of knowledge or intent.⁵² Subjecting an individual to criminal prosecution without a showing of knowledge or intent is a rare and particularly harsh government action. As industry representatives have testified to Congress, the severity of these criminal consequences render the constitutional issues even more compelling and provide a powerful argument against expanding the Agency's inspection authority any further.

Moreover, Congress has recognized that providing Agency access to food and cosmetic records could compromise the trade secrets of industry members. Congressman Hastert articulated this concern during an exchange with Commissioner Kessler in the 1991 Hearings on the Food, Drug, Cosmetic, and Device Enforcement Amendments:

MR. HASTERT: . . . The records should be considered the private property of a business. To have people swoop in and take all the records and information that a company has kept to help create a quality product, you all of a sudden create a disincentive to keep records at all. There is a great liability out there.

⁵¹ E.g., "Food, Drug, Cosmetic, and Device Enforcement Amendments," *Hearing Before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives*, 102d Cong., 1st Sess. 154-167, 168-184, 259-271 (1991).

⁵² *United States v. Dotterweich*, 320 U.S. 277 (1944); *United States v. Park*, 421 U.S. 658 (1975).

....

MR. HASTERT: . . . What would prevent somebody from your Agency from coming in, learning the [Coca-Cola] formula, or a formula like that, for instance, that is proprietary information and then several years later, once he has that information and is not in your employ any more, going out and exploiting it?

MR. KESSLER: You could go to jail, sir.

MR. HASTERT: Even if the individual does go to jail, the secret is already disclosed.

MR. KESSLER: No question, you are correct, sir, but there are very severe criminal penalties for disclosure of trade secrets, but there is that risk.

MR. HASTERT: People take those risks all the time.⁵³

Congress's determination that FDA's inspection authority for food and cosmetics should not be expanded to include the review of records thus rests on a reasoned evaluation of the issue, informed by the testimony of both the Agency and the industry.

B. For Almost A Century, The Agency Has Effectively Implemented The Food And Drug Laws Without Records Inspection Authority.

Since 1906, the Agency has effectively implemented the statute without records inspection authority for foods, and since 1938 it has done so for cosmetics. The FD&C Act provides FDA with extraordinarily broad enforcement powers, ranging from informal regulatory action for minor offenses to formal court action for major offenses. In sharp contrast to most government investigators, FDA inspectors may gain entry to establishments with no advance notice, no warrant, and no special permission from the owner or operator of the establishment. Refusal to permit an FDA inspection is a criminal offense.

The Agency consistently and effectively has used these statutory powers to implement the FD&C Act. Congress thus has found no need to increase FDA's already expansive powers to authorize records inspections for food and cosmetic establishments.

C. Enforcement Concerns Cited By The Agency Have Been Considered And Rejected By Congress When It Refused To Grant Records Inspection Authority In The Past.

The export regulation presents no unique issues of law or fact to distinguish it from the cases in which records inspection authority has been requested and denied by Congress

⁵³ "Food, Drug, Cosmetic, and Device Enforcement Amendments," note 51, *supra*, at 87.

in the past. In the context of enforcement, there is nothing to differentiate compliance with foreign law under Section 801(e)(1) of the FD&C Act from any of the other food or cosmetic provisions of the Act. If records inspection could be justified here, it could be equally justified for all other food and cosmetic issues over which FDA has jurisdiction. But FDA has already acknowledged that it has no records inspection authority in these other areas.

Thus, the enforcement concerns raised by the Agency already have been considered by Congress. Ultimately, these concerns were not sufficient to persuade Congress to grant the Agency records inspection authority for food and cosmetics.

U. S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Food and Drug Administration
Washington 25, D. C.

FOR RELEASE TO TRADE AND PROFESSIONAL JOURNALS
Thursday, August 27, 1953

The Food and Drug Administration of the Department of Health, Education, and Welfare reported today actions it has taken to put into effect the provisions of the new inspection amendment to the Federal Food, Drug, and Cosmetic Act.

Commissioner of Food and Drugs Charles W. Crawford said that FDA inspectors are now giving written notice of intention to inspect at the time when they present their credentials to the owner, operator, or agent in charge of the plant. Such notices give the date, time of day, name of the inspector and the address of the district office to which he is assigned, and the name and address of the plant.

Inspectors are also leaving written reports on conditions or practices which indicate that any products in the establishment contain filth or decomposition or have been prepared, packed or held under insanitary conditions. Inspectors leave these reports with the individual to whom they presented the notice of inspection, or if he is not available at the close of inspection, with another responsible official.

In compliance with other provisions of the new law, inspectors are now giving written receipts for all samples taken in connection with an inspection. District offices of the Food and Drug Administration will report promptly to the management of food plants the results of analyses of food samples taken in such plants for determining the presence of filth or decomposition.

In connection with these actions Commissioner Crawford said that while some phases of FDA inspections are now clearly on a mandatory basis, there are others which Congress apparently intended to be put on a voluntary basis.

In explanation he said:

"The law provides penalties for refusal to permit inspection of factories, warehouses, establishments or vehicles in which foods, drugs, cosmetics or devices are manufactured, processed, packed or held for introduction into interstate commerce, or held after such introduction, or in which they are transported, and all pertinent equipment, finished and unfinished materials, containers and labeling therein.

"Modern production and distribution are carried on to a large extent through the medium of written instructions and records. The legislative history indicates Congress did not intend to include prescription files, formula files, complaint files, and personnel files within the scope of required inspections. FDA interprets this to mean that inspection of these records will be on a voluntary basis.

"Accordingly, inspectors have been instructed to ask permission to see such records or files whenever there is any need or reason to examine them or to obtain information contained in them.

"The inspector may state reasons for asking to examine a particular record or file but will not otherwise press the owner, operator or agent for permission to see it.

"The Food and Drug Administration will not attempt to predetermine what action may be appropriate in future situations which seem to necessitate inspection of records, but will endeavor to resolve these problems as they arise, keeping in mind the health, safety and interest of consumers and the Congressional intent in the statute as a whole to protect public health.

"In 47 years since passage of the original Pure Food and Drug Law the great majority of the regulated industries have always cooperated fully in

observing its provisions and by assisting in our work of enforcement. We have every reason to believe the regulated industries will continue this cooperation."

(A copy of Public Law 217 is enclosed. Also enclosed is a copy of Public Law 201 which adopts the name, chlortetracycline, for the antibiotic, "Aureomycin".)

June 17, 2002

Appendix B

The Legislative History of Section 801(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act Demonstrates that FDA Has the Burden of Proving that Export of a Food or Cosmetic Violates Foreign Law

Section 801(e)(1)(B) of the Food , Drug, and Cosmetic Act (FD&C Act) provides that a food or cosmetic intended for export shall not be deemed to be adulterated or misbranded under the act if it:

(B) is not in conflict with the laws of the country to which it is intended for export.

This Appendix summarizes the legislative history of this provision. It establishes that (1) under the predecessor provision in the Federal Food and Drugs Act of 1906, the implementing FDA regulation took the position that the exporter was not required to furnish evidence that exported products comply with the laws of a foreign country, (2) FDA attempted but failed to persuade Congress to change that statutory approach during the consideration of the legislation that became the FD&C Act of 1938, (3) Congress explicitly amended the pending legislation in 1937 to retain the burden of proving a violation of foreign law on FDA, and (4) Congress stated in 1938 that the new law made “no substantial change” from the export provision in the 1906 Act.

I. The Federal Food and Drugs Act of 1906

Although the first bill to establish comprehensive federal regulation of domestic commerce in food and drugs was introduced in 1879, final legislation was not enacted until 1906.¹ Section 2 of the 1906 Act explicitly prohibited the “shipment to any foreign country” of any adulterated or misbranded food or drug, subject to the following exception:

Provided. That no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this Act.

This provision remained unchanged throughout the entire life of the 1906 Act.

¹ 34 Stat. 768 (1906).

Some of the food and drug bills considered by Congress prior to 1906 would have banned the export of any product that did not meet the same requirements as domestic products.² The 1906 legislation, however, unambiguously exempted exported products. Prior to the Senate debate, there was no significant discussion of this export provision. The House Report did nothing more than relate the impact of the legislation on export of regulated products, and concentrated instead on other contested provisions.³ The Senate Report was less than a page long.⁴

The rationale for the export provision was the subject of extended discussion during the Senate debate on the legislation. Senator Lodge introduced an amendment designed to make certain that United States manufacturers could pack hams in borax for shipment to Great Britain, where this practice was lawful.⁵ Senator McCumber and Senator Heyburn responded that the proviso in Section 2 already permitted such export and that a further amendment was unnecessary.⁶ Senator Heyburn, the Chairman of the Committee on Manufactures which had reported out the legislation, explained the reasons for the export proviso as follows:

Mr. HEYBURN. Mr. President, if I may add to the suggestions of the Senator from North Dakota, I will state the provisions of the bill are sufficiently drastic and specific to prohibit the transportation from State to State of this class of articles that come within the exception as to the export trade. Then we were met with the proposition that we should not attempt to enforce upon other countries the same morals in this business that we thought sufficient for our own, provided that they themselves did not think these restrictions were necessary. So, having prohibited interstate commerce in this class of articles among our own States, for which we are responsible, we made the exception that if a foreign country entertained different views in regard to the desirability of this class of packing we would not run counter to them and shut out the export trade from doing business with them simply because they ought not to be compelled to comply with restrictions necessarily adopted for our own country. That was the reason for this exceptional provision.

The Senator will find in the body of the bill that the class of articles that are within the exception as applied to the export trade are absolutely prohibited as between our own States. We are protecting our own people,

² *E.g.*, S. 3342, 57th Cong., 1st Sess. (1902); S. Rep. No. 972, 57th Cong., 1st Sess. (1902).

³ H.R. Rep. No. 2118, 59th Cong., 1st Sess. 1 (1906).

⁴ S. Rep. No. 8, 59th Cong., 1st Sess. (1905).

⁵ 40 Cong. Rec. 1129 (January 16, 1906).

⁶ *Id.* at 1129-1130. A colloquy between Senator McCumber and Senator Spooner clarified that the requirement of the proviso that the exported article not “conflict with the laws of the foreign country” was satisfied if there was no foreign law covering the matter. *Id.* at 1130.

and then we are protecting the people of other countries from imposition at the hands of our own people only to the limit that they demand such protection. But we are applying the same rule to the people governed under the laws of other countries that we apply to people governed under our own laws. That is the reason for the exception.⁷

When Senator Spooner objected on the ground that this failed adequately to protect foreign consumers, Senator Heyburn offered these further views on the matter:

The committee spent weeks and months in the consideration of this measure at this and other sessions of Congress, and we have inquired into the conditions to which this legislation was directed. That provision was not incorporated into the bill until it became apparent that there was a certain class of our export trade that did business, with the consent of the laws of the countries under which those live with whom they did business, with people who do not entertain the same views as are entertained in this country in regard to what may be necessary to preserve human health.

In other words, we ship from this country vast quantities of horse meat to be used in certain foreign countries. We do not use it at home at all. A dealer in the State of Oregon told me, having been in the business, as he said, five years, that not one single pound of that commodity had been used or consumed in this country, but that he found a market for it in the countries of Europe.

Now, if those people want that kind of a commodity, if they are presumed to be intelligent enough to determine what they want and what is conducive to their health or destructive of it, and are convinced that they have no objection to that class of commerce or commodity, there is no reason why we should constitute ourselves the guardian of their health. It is not for us to say -- except it would not be permitted to go beyond a certain line, and neither do we in this bill -- that those people shall not, in the exercise of their judgment, consume a certain class of articles.⁸

After additional spirited discussion, the Lodge amendment did not proceed to a vote at that time.⁹ Following further attempts at a compromise between Senator Heyburn and Senator Lodge¹⁰ and still further discussion,¹¹ Senator Heyburn stated that he personally felt that "the standard of our

⁷ *Id.* at 1130.

⁸ *Id.* at 1131.

⁹ *Id.* at 1135; 40 Cong. Rec. 1216 (January 18, 1906).

¹⁰ 40 Cong. Rec. 2720-2721 (February 20, 1906).

¹¹ *Id.* at 2729.

products for export should be up to the standard of our products for home consumption”¹² but that the Committee on Manufactures had voted to include the export proviso in the bill. When the final votes were taken on the Senate amendments and bill, Senator Spooner offered no objection or amendment to the export proviso and the Lodge amendment as modified in conformance with the compromise colloquy with Senator Heyburn was accepted.¹³ The Lodge amendment was not discussed or presented during the House debate,¹⁴ however, and was dropped in conference.¹⁵ Thus, the proviso in Section 2 was the sole export provision in the 1906 Act.

The first publication analyzing the 1906 Act simply paraphrased the provisions relating to export of food and drugs and provided no additional insight.¹⁶ It suggested, however, that the export proviso:

appears to be to permit the use in certain food products for export to foreign countries, of preservatives which are considered deleterious under the strict rulings of the Department of Agriculture.¹⁷

The regulations promulgated by FDA immediately after enactment of the new law contained the following pertinent provisions:

Regulation 31. Preparation of Food Products for Export.

(Section 2.)

- (a) Food products intended for export may contain added substances not permitted in foods intended for interstate commerce, when the addition of such substances does not conflict with the laws of the country to which the food products are to be exported and when such substances are added in accordance with the directions of the foreign purchaser or his agent.
- (b) The exporter is not required to furnish evidence that goods have been prepared or packed in compliance with the laws of the foreign

¹² *Id.* at 2730.

¹³ 40 Cong. Rec. 2769 (February 21, 1906).

¹⁴ A simple amendment to permit one percent borax as a food preservative was defeated. 40 Cong. Rec. 9075 (June 25, 1906).

¹⁵ S. Doc. No. 521, 59th Cong., 1st Sess. (1906); H.R. Rep. No. 5056, 59th Cong., 1st Sess. (1906); H.R. Rep. No. 5096, 59th Cong., 1st Sess. 1906).

¹⁶ Arthur P. Greeley, *The Food and Drugs Act June 30, 1906: A Study* 9 (1907).

¹⁷ *Id.*

country to which said goods are intended to be shipped, but such shipment is made at his own risk.

- (c) Food products for export under this regulation shall be kept separate and labeled to indicate that they are for export.
- (d) If the products are not exported they shall not be allowed to enter interstate commerce.¹⁸

These regulations were not changed for the entire history of the 1906 Act.

In 1920, FDA issued a manual containing instructions to its employees about enforcement of the 1906 Act.¹⁹ The two pages relating to examination of export foods²⁰ were devoted to reconciling the annual appropriations for voluntary examination and certification of exported food in order to facilitate acceptance of United States food products abroad, with the proviso in Section 2 of the 1906 Act that permitted the export of adulterated and misbranded food. FDA determined that food found to be in violation of the 1906 Act would not be eligible for certification under the appropriations statute but would be permitted to be exported under the 1906 Act.

During the thirty-two-year history of the 1906 Act, two court opinions were published relating to the export of adulterated and misbranded food and drugs. In the first case,²¹ adulterated tomato paste was shipped from New Jersey to Philadelphia to be examined to determine whether, although it was illegal under the 1906 Act, it could nonetheless meet the English standard and thus could be exported to a customer in London. The court recognized that, if the English standard had been satisfied, the food could have been exported lawfully. Because the adulterated product was initially shipped in interstate commerce rather than directly abroad, however, the condemnation was upheld.

In the second case,²² FDA seized sacks of dried figs that were about to be loaded aboard a ship for export, on the ground that they consisted partly of filthy, decomposed, or putrid vegetable matter and thus were adulterated. In a split decision, the court of appeals held that the adulterated figs could properly be exported under the proviso in Section 2 of the 1906 Act. FDA introduced in evidence the provisions of the Austrian law prohibiting some types of impure food materials. The majority of the court concluded, however, that this was inadequate to show that the ultimate use of the product abroad would conflict with the laws of the foreign country,

¹⁸ USDA, *Rules and Regulations for the Enforcement of the Food and Drugs Act*, Office of the Secretary Circular No. 21 at 12-13 (October 16, 1906), reprinted in S. Doc. No. 252, 59th Cong., 2d Sess. (1907).

¹⁹ Bureau of Chemistry, *The Food and Drug Manual* (1920).

²⁰ *Id.* at 136-137.

²¹ *Philadelphia Pickling Co. v. United States*, 202 Fed. 150 (3d Cir. 1913).

²² *United States v. Catz American Co., Inc.*, 53 F.2d 425 (9th Cir. 1931).

because the manufacturer might well cull out the deleterious matter before using the remaining material for food or, if that were not possible, might divert the shipment to other proper uses. The dissent argued that the proviso in Section 2 should not be interpreted to apply to decayed food in its natural condition.

In an unreported district court case,²³ FDA seized adulterated apple chops after they had been shipped from the state of Washington to California for export to France. FDA argued that the requisite interstate commerce had been shown, but the court held that the shipment fell within the proviso of Section 2.

Thus, the courts as well as FDA unequivocally placed the burden of showing a violation of foreign law on FDA.

II. The Federal Food, Drug, and Cosmetic Act of 1938

As early as the 1917 Annual Report,²⁴ FDA identified deficiencies in the 1906 Act that required legislative correction. The proviso in section 2, however, was not mentioned as a problem.

A. The Export Provision

In 1933, when Senator Royal S. Copeland introduced the first bill, S. 1944, that was to become the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938, the legislation contained no exemption for exported articles.²⁵ During hearings on S. 1944, several industry representatives objected to this omission. Testimony on behalf of the Pacific Northwest fruit and vegetable industry suggested that the definition of interstate commerce be amended to exclude exports:

The reason for this change is that it is unreasonable to require American manufacturers and processors of food products to meet standards and tolerances which are not requirements of the countries to which the food is exported. In the field of international competition, the American exporter would be greatly handicapped by this unreasonable restriction. The present act amply covers this point by the provision that such commerce shall not be in violation of the laws of foreign countries of destination.²⁶

²³ FDA, *1935 Report of Food and Drug Administration* 19, reprinted in Food Law Institute, *Federal Food, Drug, and Cosmetic Law Administrative Reports 1907-1949* 825, 843 (1951).

²⁴ Bureau of Chemistry, *1917 Report of Bureau of Chemistry*, reprinted in Food Law Institute, note 75 *supra*, at 355, 366.

²⁵ S. 1944, 73d Cong., 1st Sess. (1933). The lack of any provision regarding exports was not mentioned when the bill was introduced. 77 Cong. Rec. 5721 (June 12, 1933).

²⁶ "Food, Drugs, and Cosmetics," *Hearings Before a Subcommittee of the Committee on Commerce, United States Senate, 73d Cong., 2d Sess.* 426 (1933) (1933 Senate Hearings).

A representative of the National Cannery Association offered a similar amendment,²⁷ and the California Fruit Exchange also argued against applying United States restrictions to the export trade.²⁸

At the conclusion of the 1933 hearings, Senator Copeland revised the proposed legislation in response to some of the issues raised by witnesses.²⁹ Section 20(d) of the revised bill, S. 2000,³⁰ provided that:

- (d) A food, drug, or cosmetic intended for export which is not adulterated within the meaning of section 3, paragraph (a); section 4, paragraph (a); or section 5 shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) complies with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the package with the words, "For Export." But if such article is sold or offered for sale in domestic commerce, this paragraph shall not exempt it from any of the provisions of this Act.

Compared to the 1906 Act, which permitted the export of any food or drug that accorded to the specifications of the foreign purchaser and was not in conflict with the laws of the receiving country, this bill and its successor, S. 2800,³¹ exempted food, drugs, and cosmetics only from the misbranding provisions and selected adulteration provisions of the bill. Section 20(d) of S. 2800 would have barred the export of a food bearing or containing a poisonous or deleterious substance or consisting of any filthy, decomposed, or putrid substance. A drug that was dangerous to health under the conditions of use prescribed in its labeling could not be exported. A cosmetic containing a poisonous or deleterious substance in such quantity as to render it injurious to the user under its labeled conditions of use could not be exported.

A representative of the California State Chamber of Commerce, Agriculture and Industry, the Dried Fruit Association of California, and the Northwest Dried Fruit Association, testified against this export provision, arguing that it would severely hamper the position of United States producers in international trade.³² Instead of the restrictive export provision contained in Section 20(d) of S. 2800, it was suggested³³ that the Committee adopt the language

²⁷ *Id.* at 389.

²⁸ *Id.* at 477.

²⁹ *Id.* at 494.

³⁰ 73d Cong., 2d Sess. (1934). See 78 Cong. Rec. 59 (January 4, 1934).

³¹ 73d Cong., 2d Sess. (1934). See 78 Cong. Rec. 2728 (February 19, 1934).

³² "Food, Drugs, and Cosmetics," *Hearings Before the Committee on Commerce, United States Senate*, 73d Cong., 2d Sess. 454-455 (1934) (1934 Senate Hearings).

³³ *Id.* at 455.

in Section 16(b) of the competing McCarran-Jenckes bill, which provided that the law would not apply:

to any food, drug, or cosmetic shipped or delivered for shipment for export to a foreign country, in a form complying with the laws of such country and acceptable to the foreign consignee: Provided, That if such article is diverted for domestic use and remains in commerce it shall become subject to this Act.³⁴

Alternatively, it was urged that the export language of Section 2 of the 1906 Act be retained because "It has the benefit of court decisions, making it understood and accepted in export trade, under which a very large export business has been built up in agricultural commodities."³⁵

FDA Commissioner Walter G. Campbell argued for strict export standards:

My thought is this: Without undertaking any undue solicitude about the welfare of consumers in other nations, it would be inhuman not to restrict the shipment of products that would be deleterious to health to the foreign consumers, products that we would not permit to be marketed in this country; also products which are filthy, putrid, or decomposed. If that practice is permitted on the part of a few who might desire to do it, it would compromise the standing and the reputation of American food and drug producers.³⁶

Senator Herbert observed that protecting the reputation of United States manufacturers was not the purpose of the bill, and Mr. Campbell conceded that "There can be no brief held for that provision if it is the purpose of the Congress to have us confine ourselves to the food and drugs that are to be consumed by Americans."³⁷

When S. 2800 was reported out of the Commerce Committee in 1934,³⁸ the export provision was revised to drop the requirement that foods, drugs, or cosmetics intended for export not be adulterated. The new provision, substantially the same as the one ultimately enacted, provided that:

- (d) A food, drug, 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) complies with the laws of the country to which it is intended for export, and (3) is labeled on the

³⁴ S. 2858, 73d Cong., 2d Sess. (1934).

³⁵ 1934 Senate Hearings at 455.

³⁶ *Id.* at 522.

³⁷ *Id.*

³⁸ 78 Cong. Rec. 4567 (March 15, 1934).

outside of the shipping package with the words "For Export." But if such article is sold or offered for sale in domestic commerce, this paragraph shall not exempt it from any of the provisions of this act.³⁹

The Senate Report explained this provision as follows:

Section 2 of the existing law contains a proviso setting up exemptions for articles offered for export to foreign countries. This provision would be continued in substantially the same form by paragraph (d) of this section. It should be noted that this paragraph would require only those goods to be marked "For export" which did not conform with the requirements of the law applicable to domestic trade.⁴⁰

Thus, Congress rejected FDA's request for a narrower export policy and adopted instead the 1906 Act policy that permitted the export of any article that complied with applicable foreign law.

That this language was a substantial liberalization of the export provision was clearly understood by witnesses who addressed the issue during hearings on S. 5, the successor to S. 2800 in the following year.⁴¹ A representative of the National League of Women Voters, for example, testified that:

As this is drawn up, the United States manufacturer may export foods, drugs, and cosmetics to any country; provided, as I understand it, the laws of that country would permit the acceptance of those exports. That, as we feared, would permit this country to export adulterated foods, drugs, and cosmetics. I am afraid I still shudder over the testimony that appeared before you last year in the question of the wormy figs. I think about those every once in a while. We realize that most of the European countries do have food and drug laws, and that a good many South American countries have, but many of the eastern countries and the oriental countries have laws which do not protect the people who would buy, and we should like very much to see this clause strengthened so that the reputation of American goods may not be injured by the exporting to other countries of distinctly inferior products.⁴²

Similarly, the Association of Dairy, Food, and Drug Officials of the United States explained its understanding of the export provision that it "exempts from the act any food, drug, or cosmetic

³⁹ *Id.* at 4571.

⁴⁰ S. Rep. No. 493, 73d Cong., 2d Sess. 22 (1934).

⁴¹ S. 5, 74th Cong., 1st Sess. § 714(d) (1935).

⁴² "Foods, Drugs, and Cosmetics," *Hearings Before a Subcommittee of the Committee on Commerce, United States Senate, 74th Cong., 1st Sess. 39-40 (1935) (1935 Senate Hearings).*

intended for export and so labeled, so long as it complies with the law of the country to which it is intended for export.”⁴³

The Dried Fruit Association of California sought a further change in the provision. Instead of stating in subsection (d)(2) that a product could be exported “if it complies with the laws of the country to which it is intended for export,” they asked to:

have that put the other way around and to have it read: “Provided it does not violate the law of the country to which it is exported”.⁴⁴

In a supplemental submission to the Subcommittee, the Association explained that:

Our sole purpose in suggesting this present amendment is to preserve the existing court decisions on this point and not word the act in such a way as the burden of proof in compliance might be placed upon the shipper rather than the burden of proof in violation being placed upon the Government.⁴⁵

The language of the export provision remained substantially the same during the various revisions of the bill that followed the close of formal hearings. But in 1937, the revision of the export provision suggested by the Dried Fruit Association of California became part of Committee Print No. 3 of S. 5 during its consideration in the House of Representatives. It remained this way through final enactment of the 1938 Act⁴⁶ and has not been substantively amended since.

This review of the legislative history of the export provision demonstrates that Congress began by considering a bill that would have substantially tightened the export provision, and then revised the provision continuously so that it would preserve in substantially the same form the export exemption contained in the 1906 Act. Indeed, the House Report on the final 1938 Act explained that section 801 made “no substantial change from the provisions of the present law.”⁴⁷ In so doing, Congress rejected legislation that would have barred the export of adulterated food, drugs, and cosmetics or placed the burden of demonstrating compliance with foreign law on the exporter.

⁴³ *Id.* at 177.

⁴⁴ *Id.* at 202.

⁴⁵ *Id.* at 205.

⁴⁶ 52 Stat. 1040 (1938).

⁴⁷ H.R. Rep. No. 2139, 75th Cong., 3d Sess. 13 (1938).