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President

August 16, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, Maryland 20852

Re: Recordkeeping Requirements for Exports of Food and Cosmetics
Advance Notice of Proposed Rulemaking
Docket No. 1998N-0583
69 Fed. Reg. 30842 (June 1, 2004)

The Grocery Manufacturers of America (GMA) and the Cosmetic, Toiletry, and Fragrance Association (CTFA) submit these comments in response to the advance notice of proposed rulemaking (ANPR) published by the Food and Drug Administration (FDA) to solicit comment on recordkeeping requirements relating to compliance with foreign law for exported food and cosmetics.

GMA is the world's largest association of food, beverage, and consumer product companies. Led by a board of 42 chief executive officers, GMA applies legal, scientific, and political expertise from its more than 140 member companies to vital public policy issues affecting its membership. The association leads efforts to increase productivity, efficiency, and growth in the food, beverage, and consumer products industry. With United States sales of more than \$500 billion, GMA members employ more than 2.5 million workers in all 50 states.

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CTFA is the national trade association representing the personal care product industry. Founded in 1894, CTFA represents almost 600 companies that manufacture or distribute the vast majority of finished personal care products marketed in the United States, and companies from related industries, including manufacturers of raw materials, packaging materials, and research testing laboratories.

The members of GMA and CTFA export a large portion of food and cosmetics manufactured in the United States, in accordance with Section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Accordingly, GMA and CTFA have a vital interest in the recordkeeping requirements relating to compliance with foreign law, initially promulgated as Section 1.101(b)(2) of the FDA regulations in 66 Fed. Reg. 65429 (December 19, 2001). In response to a Petition for Reconsideration and Stay of Action submitted by GMA and CTFA, these requirements were stayed for reconsideration under this ANPR.

The Relevant Statutory Provision

Section 801(e)(1) of the FD&C Act provides that a food or cosmetic intended for export shall not be deemed to be adulterated or misbranded if it:

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

This provision of the FD&C Act has remained unchanged since it was enacted in 1938. FDA issued no regulations to interpret or implement it prior to the provisions promulgated in December 2001 and subsequently stayed.

The Relevant Portion of the Stayed Regulations

The first sentence of Section 1.101(b) of the regulations promulgated in December 2001 requires that persons exporting a food or cosmetic under Section 801(e)(1) of the FD&C Act shall maintain records as enumerated in paragraphs (b)(1) through (b)(4), demonstrating that the product meets the provisions of Section 801(e)(1). GMA and CTFA made no objection to this requirement and did not request that it be stayed. Accordingly, this requirement is presently in effect.

Section 1.101(b)(2) of the regulations requires that persons exporting a food or cosmetic under Section 801(e)(1) of the FD&C Act must maintain records demonstrating that the product does not conflict with the laws of the importing country, and provides that such records may consist of either a letter from a foreign government or a notarized certification by a responsible company official. It is this specific requirement to which GMA and CTFA objected, and which FDA subsequently stayed for reconsideration.

Records Demonstrating That the Product Does Not Conflict
With the Laws of the Importing Country

GMA and CTFA emphasize that they have no objection to the generalized requirement in Section 1.101(b)(2) of the regulations that persons exporting an article under Section 801(e)(1) of the FD&C Act must maintain records demonstrating that the product does not conflict with the laws of the importing country. If Section 1.101(b)(2) of the regulations had ended there, GMA and CTFA would not have filed its Petition for Reconsideration and Stay of Action with respect to this portion of the regulations. GMA and CTFA have made it clear that a generalized requirement for maintenance of records demonstrating compliance with Section 801(e)(1)(B) would be consistent with good business practice and thus would raise no concern

within the regulated industry. Company employees regularly review foreign laws and regulations to verify compliance of exports with Section 801(e)(1)(B) and maintain records of their determinations. Thus, the preamble to the ANPR (69 Fed. Reg. at 30843) correctly relates that, in correspondence with FDA, GMA and CTFA have said that there can be no objection from a policy standpoint to a general requirement that every company must have adequate documentation in its files to support its conclusion that an exported product that does not comply with the FD&C Act does not violate the laws of the foreign country to which it is exported. GMA and CTFA reaffirm this position.

The Requirement of a Letter from a Foreign Government
or a Notarized Certification by a Company Official

Following the general recordkeeping requirement in the initial portion of Section 1.101(b)(2), however, the remainder of the regulation goes on to say that the recordkeeping requirement “may” consist of either of a letter from the foreign government or a notarized certification by a responsible company official. It was this specificity to which GMA and CTFA objected, and which resulted in the Petition for a Reconsideration and Stay of Action.

The wording of this portion of the regulation is ambiguous. Following discussion with FDA officials at the time, GMA and CTFA interpreted it to state that FDA would require either the specified letter or the specified certification, and would not regard as acceptable the types of normal business records that have been maintained since 1938 to show compliance with Section 801(e)(1)(B). FDA now raises the possibility, in the preamble to the ANPR (69 Fed. Reg. at 30843), that the term “may” was intended to be taken literally, *i.e.*, that the letter or certification are merely options, not requirements, and that the types of records maintained by food and cosmetic exporters since 1938 would be equally acceptable.

If FDA in fact intended the word “may” to achieve the type of flexibility sought by GMA and CTFA, and will now confirm that interpretation, this matter is ended. The only reason that GMA and CTFA objected to this portion of the final regulations was because it appeared that the letter and certification approaches were the only two permitted options, and that the types of normal business records maintained since 1938 would no longer be acceptable. If those traditional business records are in fact acceptable, and FDA confirms this interpretation of the provision, GMA and CTFA hereby withdraw all of their objections to this provision.

A Letter from a Foreign Government

As anyone who has ever tried to do it knows, it is virtually impossible to obtain a letter from a foreign government agency, department, or other authorized body stating that a food or cosmetic either has marketing approval from the foreign government or does not conflict with that country’s laws. United States companies export thousands of products each year to foreign countries located throughout the world. Many foreign countries simply have no staff to provide letters of the type envisioned under this provision, and what staff may exist clearly has higher priorities. If foreign countries were called upon to provide the thousands of letters described by this provision, the system would simply break down. Thus, the option of obtaining a letter from a foreign country for a food or cosmetic product is a dead letter. It could never be used.

A Notarized Certification by a Responsible Company Official

The second option provided by this provision is to obtain a notarized certification by a responsible company official in the United States that the product does not conflict with the laws of the importing country. Because this is within the control of the company exporting the

food or cosmetic, unlike the first option this one is at least feasible. The sole issue here is whether it is unnecessarily burdensome.

GMA and CTFA strongly believe that, from a public policy standpoint, mandatory application of this approach to all exports of food and cosmetics cannot be justified. It would result in enormous cost, with no corresponding benefit.

One simple example should be sufficient to demonstrate the problem that industry would face. Every food or cosmetic product exported from the United States to Canada is required to conform to the Canadian laws and regulations governing these products. The regulatory requirements imposed by Canada for these products differ from those imposed by FDA. Accordingly, products made in the United States and labeled for compliance with Canadian requirements invariably are "misbranded" under the FD&C Act and thus can only be exported in compliance with Section 801(e)(1)(B). All of these exports would, as a practical matter, need a notarized certification by a responsible company official, because a letter from the Canadian government would be impossible. Even the slightest change in formulation -- *e.g.*, the customary variations in vegetable oils in food products, or the traditional wide range of colors for a line of lipsticks -- would require an individual notarized certification. The cost, much less the logistics, would be staggering.

It takes little imagination to foresee what would happen. Every company would set up a Department of Export Certification, with a responsible official at the head and a staff to prepare the requisite certifications. The head of the new department would then be responsible for notarizing all certifications.

What happens today, in contrast, is that a company's regulatory affairs department maintains a centralized record of, for example, the color additives permitted for use in countries throughout the world. When a color additive is proposed for use in a new or reformulated food or cosmetic that is to be exported to a specific foreign country, it is a simple matter to check this central database in order to verify that it may lawfully be used in that country. There is no need for a separate record for each product, much less a certification and notarization. Regulatory affairs personnel throughout the food and cosmetic industries are accustomed to assuring compliance with both foreign and domestic laws and regulations on this basis, with a minimum of expense and resources. A formal approach, requiring a notarized certification, simply cannot be justified on a cost-benefit basis for exports any more than it could be for domestic products.

GMA and CTFA are not aware of any evidence that United States food and cosmetic companies have been exporting significant quantities of food and cosmetics to foreign countries that have been found to violate the laws of those countries. None of the preambles to the proposed and final regulations and to this ANPR put forth any evidence of a significant problem of noncompliance with foreign law. Food and cosmetic companies have been exporting their products to foreign countries under Section 801(e)(1) since 1938 -- and food companies have exported their products under a comparable provision since 1906 -- without incurring significant foreign objections. Accordingly, a massively expensive program would only raise cost and prices, and would provide no greater protection of foreign countries than exists today.

An Intermediate Approach

As the preamble to the ANPR points out (69 Fed. Reg. at 30843), in an attempt to find a practical middle ground and to avoid a legal confrontation, GMA and CTFA offered the possibility that the notarized certification requirement would only apply where there was in fact a substantial safety concern, *e.g.*, where there is a label warning required by FDA or a specific limit on the presence of an ingredient because of substantial safety concerns. This would dramatically reduce the burden of notarized certifications, because label warnings and substantial safety concerns are rare for food and cosmetic products.

The ANPR raises the issue whether this type of situation could be adequately described in an FDA regulation. GMA and CTFA believe that FDA can prepare a regulation that adequately restricts the requirement of a notified certification to matters that raise “substantial safety concerns.” The FD&C Act and FDA regulations are replete with phrases that are no more detailed than “substantial safety concerns,” and FDA and industry have learned how to implement them. The task of defining “substantial safety concerns” is no more difficult than preparing the numerous regulations that implement many other general provisions of the FD&C Act.

Other Alternatives

GMA and CTFA recommend against other alternatives, that would undoubtedly entail much more substantial resources and costs. There has been no epidemic of non-compliance with foreign laws by United States exporters of food and cosmetics. The requirements of Section 801(e)(1)(B) have been adequately complied with by the American food and cosmetic industries since 1938, without the need for implementing regulations. It is

sufficient, as noted above, simply to keep the first portion of Section 1.101(b)(2), which in general terms requires persons who export a food or cosmetic to maintain records demonstrating that the product does not conflict with the laws of the importing country. That is the statutory obligation, and nothing more is needed. And if FDA wishes to retain the current two stated options -- a letter from a foreign government or a notarized certification -- as nonmandatory examples, GMA and CTFA would have no objection. To impose substantial new regulatory requirements with no documented benefit is, however, unwise public policy.

A Legal Analysis

GMA and CTFA seek to resolve this matter on a practical, rather than a legal, basis. Nonetheless, it is appropriate to review the statutory language and its legislative history in order to determine the proper legal interpretation of Section 801(e)(1)(B) of the FD&C Act.

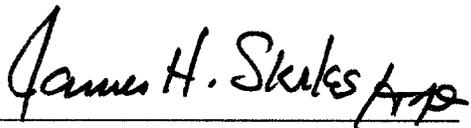
Attached to these comments, as an Appendix, is a comprehensive and detailed legislative history of the development of Section 801(e)(1)(B) from 1906 to 1938. Under the Food and Drugs Act of 1906, FDA and the courts recognized that the Agency had the burden of proving that an exported food that did not comply with the 1906 Act was not in compliance with the laws of the foreign country to which it was exported, and therefore could not lawfully be exported from our country. Throughout the history of the FD&C Act from 1933 to 1938, FDA sought to shift the burden of proof of compliance with foreign law from the Agency to the exporter. In the end, FDA failed to achieve this objective. In 1937, the draft legislation was changed specifically to place the burden of proof on FDA rather than on the exporter. This is confirmed by the House Report on the final 1938 Act, which stated that Section 801 made "no substantial change from the provisions of the present law." Thus, as a matter of statutory law,

FDA bears the burden of demonstrating that a person who exports a food or cosmetic from the United States to a foreign country is violating the law of the foreign country. It is not incumbent on the person exporting the product to prove that it complies with the foreign law.

As already noted, however, GMA and CTFA have not sought to resolve this matter on a strict interpretation of the FD&C Act. Because it is sound business practice for all industries to maintain records demonstrating compliance with applicable laws and regulations, the food and cosmetic industries raise no objection to a general requirement that exporters maintain records demonstrating that an exported product does not conflict with the laws of the importing country.

Conclusion

For all of these reasons, GMA and CTFA recommend that all but the initial three lines (i.e., everything after the colon) in Section 1.101(b)(2) be deleted.



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Attachment

August 16, 2004

Appendix

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

Section 801(e)(1)(B) of the Federal 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.

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

¹ 34 Stat. 768 (1906).

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).

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, 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:

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.

⁷ *Id.* at 1130.

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 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

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.

¹² *Id.* at 2730.

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.

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.*

- (b) The exporter is not required to furnish evidence that goods have been prepared or packed in compliance with the laws of the foreign 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

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).

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, 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.

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

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).

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.

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

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.

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).

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 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

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.

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

³⁵ 1934 Senate Hearings at 455.

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 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

³⁶ *Id.* at 522.

³⁷ *Id.*

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

³⁹ *Id.* at 4571.

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

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 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

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)*.

⁴³ *Id.* at 177.

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 in the 1938 Act 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

⁴⁴ *Id.* at 202.

⁴⁵ *Id.* at 205.

⁴⁶ 52 Stat. 1040 (1938).

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.

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