



E. Edward Kavanaugh  
President

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

Re: Record Requirements for Cosmetics Containing  
Material from Cattle  
Notice of Proposed Rulemaking  
Docket No. 2004N-0257  
69 Fed. Reg. 42275 (July 14, 2004)

The Cosmetic, Toiletry, and Fragrance Association (CTFA) submits these comments in response to the proposed regulation published by the Food and Drug Administration (FDA) to solicit comment on record requirements for cosmetics containing material from cattle. The proposed regulation, which is intended to help prevent contamination of cosmetics from bovine spongiform encephalopathy (BSE), is intended to replace the record provisions of the interim final regulation published in the same issue of the *Federal Register*.

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. Members of CTFA are therefore deeply interested in the record provisions of the proposed regulation.

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### The Interim Final Regulation

In 69 Fed. Reg. 42256 (July 14, 2004), FDA issued an interim final regulation for use in cosmetics of materials derived from cattle. Section 700.27(b) provides that “No cosmetic shall be manufactured from, processed with, or otherwise contain, prohibited cattle materials.” The term “prohibited cattle materials” is defined in Section 700.27(a)(1) to include five types of cattle materials, but specifically to exclude “tallow that contains no more than 0.15 percent hexane-insoluble impurities and tallow derivatives.” The term “tallow” is defined in Section 700.27(a)(6) to require that if it is to be allowed for use in cosmetics, it “must be free of prohibited cattle risk material or must contain not more than 0.15 percent hexane-insoluble impurities.” The term “tallow derivative” is defined in Section 700.27(a)(7) to mean “any chemical obtained through initial hydrolysis, saponification, or transesterification of tallow.”

Section 700.27(c) of the interim final regulation requires manufacturers of cosmetics that contain cattle material of any kind to make existing records relevant to compliance with the regulation available to FDA for inspection and copying. FDA intends that Section 700.27(c) of the interim final regulation will remain effective while the proposed regulation that is the subject of these comments is under consideration.

### The Proposed Regulation

The proposed regulation that is the subject of these comments would amend Section 700.27(c) of the interim final regulation to expand the recordkeeping requirements applicable to the use of material from cattle in cosmetics. The heart of the proposed regulation is in Section 700.27(c)(1), which would require the manufacturer of a cosmetic that contains any

type of material from cattle to “establish and maintain records sufficient to demonstrate that the cosmetic is not manufactured from, processed with, or does not otherwise contain, prohibited cattle materials.” Consistent with the interim final regulation, prohibited cattle materials excludes tallow and other cattle materials that are free of prohibited cattle risk material, tallow that contains no more than 0.15 percent hexane-insoluble impurities, and tallow derivatives.

#### Voluntary Cooperation by the Cosmetic Industry

The cosmetic industry fully appreciates the public health significance of BSE. CTFA and its members have worked diligently to assure that cosmetic products are free from potential BSE contamination. The industry has worked closely with FDA and foreign governments to avoid the use in cosmetic products of any ingredients that might contain BSE.

For decades, moreover, members of the cosmetic industry have routinely cooperated with FDA to take whatever action is needed -- including voluntary disclosure of production and distribution records -- whenever any issue of significant public health concern has been raised. Although Section 704 of the FD&C Act does not require that cosmetic manufacturers provide their records to FDA, companies respond to any reasonable FDA request for these records. CTFA has urged its members to continue this tradition of cooperation with FDA with respect to all records that could bear upon the contamination of cosmetic products with prohibited cattle materials. As in the past, the cosmetic industry will approach this matter on the basis of public health protection rather than strict legal analysis.

#### The Categories of Permitted Cattle Materials

Under Section 700.27(b), no cosmetic may contain prohibited cattle materials. Section 700.27(a)(1) and (6) reinforce this by providing that tallow must be free of prohibited

cattle risk material (or must contain no more than 0.15 percent hexane-insoluble impurities).

Accordingly, tallow -- and other cattle materials -- that contain no prohibited cattle materials are, under these regulations, permitted to be used in cosmetics.

In addition to the provisions in Sections 700.27(a)(1) and (6) that permit the use in cosmetics of tallow and other cattle materials that contain no prohibited cattle materials, Section 700.27(a)(1) defines two other categories of cattle materials that are excluded from the definition of prohibited cattle materials and thus are also permitted for use: (1) tallow that contains no more than 0.15 percent hexane-insoluble impurities and (2) tallow derivatives that are obtained through initial hydrolysis, saponification, or transesterification of tallow. FDA has appropriately determined that these two categories of excluded cattle materials raise no significant issue of BSE contamination of cosmetics. CTFA and its members agree that these materials are safe and need not be prohibited from cosmetics.

Under the interim final regulation, milk is prohibited from use in cosmetics as “prohibited cattle materials” because the cattle from which it comes are “not inspected and passed.” We are confident that FDA did not intend this result. Milk and its byproducts should therefore be excluded from Section 700.27(a)(1).

#### The Need for Special Records Regarding the Permitted Cattle Materials

The categories of permitted cattle materials -- tallow and other cattle materials that contain no prohibited cattle materials, tallow that contains no more than 0.15 percent hexane-insoluble impurities, and tallow derivatives -- which FDA and CTFA agree raise no risk of BSE, and thus are completely safe for use in cosmetics, encompass a wide variety of ingredients that are often used in cosmetics. Tallow produced with no prohibited cattle materials

or with less than 0.15 percent hexane-insoluble impurities is a common cosmetic ingredient, and tallow is a common starting material, with desirable chemical properties, that can be converted easily to derivative products that serve a wide variety of important cosmetic functions. Other cattle materials such as milk, milk byproducts, and gelatin are also common ingredients in cosmetics.

As FDA has recognized, these categories of cattle material products raise no different or greater safety issues than any other cosmetic ingredient. There is therefore no greater justification for special record requirements -- including access to company records -- for these permitted types of cattle material products than there is for any other cosmetic ingredient.

Proposed Section 700.27(c) would establish requirements for these permitted categories of cattle material products that are substantially more comprehensive and onerous than any other cosmetic ingredient. In effect, it would require cosmetic manufacturers to keep separate records relating to these ingredients as contrasted with ingredients from any other source.

Tallow. The types of records that the cosmetic industry can receive and generate with respect to any ingredient provide the supplier identity, and chemical specifications for the substance or mixture. With respect to tallow and similar permitted cattle ingredients, this type of record should be sufficient for compliance with the regulation.

CTFA recommends that FDA revise the proposed regulation to make it clear that a cosmetic manufacturer is not required to prove that tallow or similar cattle material ingredient (e.g., milk and gelatin) does not contain prohibited cattle materials. The regulation should instead require the finished cosmetic manufacturer to retain, as manufacturers do now, records

that state the supplier, identity, and specifications (including that it contains no prohibited cattle materials) for the ingredient. This will determine whether any material derived from cattle fits within one of the categories of permitted cattle materials set forth in the regulation and will allow FDA to trace the product back to its origin if that were to become necessary.

If FDA concludes that some additional assurance is needed, it would be feasible for a cosmetic company to obtain from its ingredient supplier a guarantee under Section 303(c)(2) of the FD&C Act, in the form suggested in Section 7.13 of the FDA regulations, stating that the ingredient is not manufactured from or processed with, and does not otherwise contain, prohibited cattle materials. The manufacturer of a cosmetic cannot, however, be held accountable for personally supervising the production and distribution of permitted tallow and related cattle material products from their origin all the way through to final delivery to the finished cosmetic manufacturing establishment. Any such requirement would be unduly burdensome and not justified for ingredients that FDA itself has determined to be safe.

Tallow Derivatives. For tallow derivatives, there is an even more difficult problem. Many chemicals can be produced using either tallow or another product (e.g., vegetable oil) as the starting material. The finished cosmetic manufacturer -- and undoubtedly the various intermediate distributors -- do not know the starting material. As the proposed regulation is now written, the finished cosmetic manufacturer would be required to keep special records on all chemicals that could conceivably be made from tallow, to show that prohibited cattle materials are not included.

CTFA therefore recommends that tallow derivatives be excluded from the special recordkeeping requirements. In light of FDA's determination that these chemicals present no human BSE risk, the recordkeeping burden is unjustified.

#### Records Inspection

For the reasons set forth above, the cosmetic industry has determined that it will continue its long tradition of cooperation with FDA by making available, on a voluntary basis, the types of records described above that reflect the use in cosmetic products of permitted tallow ingredients, *i.e.*, those that are not prohibited. The industry has concluded that it is important to reassure FDA and the public that its products raise no potential risk of BSE contamination.

For the record, CTFA is constrained to note that FDA has no authority under the FD&C Act to require records inspection under these or any other circumstances. Attached to these comments is an Appendix containing a comprehensive and detailed legal analysis of this matter. As these comments make clear, however, this legal analysis is correct, but primarily of academic interest with respect to the current proposed regulation because the cosmetic industry intends to make the pertinent records available on a voluntary basis regardless of the lack of FDA statutory authority to require their production.

#### Effective Date

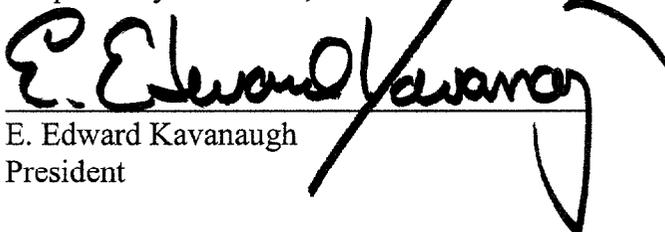
The proposed effective date for the final regulation is 30 days after publication (69 Fed. Reg. at 42278). CTFA requests that at least 90 days be provided before the final regulation becomes effective. Changes in internal recordkeeping cannot be accomplished overnight in either small or large companies. It will take at least 90 days to review the final regulation and the explanatory preamble, examine and revise existing company standard

operating procedures (SOPs), issue new SOPs, and achieve adequate implementation. In the interim, the public health will be fully protected by the continuing applicability of Section 700.27(c) of the interim final regulation.

Conclusion

For the foregoing reasons, CTFA recommends that Section 700.27(c)(1) of the proposed regulation be clarified to provide that records documenting the identity and chemical specifications of ingredients will be sufficient to demonstrate the absence of prohibited cattle materials or, if that is not sufficient, that an appropriate guarantee under Section 303(c)(2) of the FD&C Act, in the form suggested in Section 7.13 of the FDA regulations, will be sufficient for this purpose. CTFA also recommends an effective date at least 90 days after publication of the final regulation.

Respectfully submitted,

  
E. Edward Kavanaugh  
President

Cc: Robert E. Brackett, Ph.D.  
Linda M. Katz, M.D.

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Appendix

**FDA Has No General Authority Under the Federal Food, Drug, and  
Cosmetic Act to Require Manufacturers of Food or Cosmetics to  
Disclose Company Records to FDA Inspectors**

This Appendix demonstrates that FDA has no statutory authority to require Agency inspection of company records relating to compliance of food or cosmetics with the Federal Food, Drug, and Cosmetic Act (FD&C Act) except under limited circumstances for food that are not relevant here. Because the FDA inspection authority under Section 704 of the FD&C Act is identical for food and cosmetics, any reference in this Appendix to either is equally applicable to the other.

**I. The Records Inspection Provisions of the Interim Final and Proposed Regulations Exceed 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 except under limited conditions for food discussed in Parts I(B) and II(I) and (L) below, which are not relevant to the interim final and proposed regulations. Section 703 authorizes FDA inspection only of records documenting interstate shipment of food and cosmetics. 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 a

category of products -- for prescription drugs,<sup>1</sup> specified medical devices,<sup>2</sup> infant formula<sup>3</sup>, and human nonprescription drugs<sup>4</sup> -- 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, specified medical devices, infant formula, and human nonprescription drugs, would be superfluous.

FDA has sought records inspection authority for food and cosmetic 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 FDA and industry representatives, Congress has been able to consider the competing interests involved, and has determined repeatedly that records inspection authority is not warranted for food or cosmetic products. Congress has relied on the excellent cooperation of the industry in voluntarily providing relevant records to FDA whenever an issue of public health concern has arisen.

**B. The Inspection of Records for Food and Cosmetics Is Not Authorized Under Sections 701(a) and (b) of the FD&C Act.**

Section 701(a) of the FD&C Act provides that FDA has the authority to promulgate regulations for the efficient enforcement of the FD&C Act generally and Section

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<sup>1</sup> 76 Stat. 780, 792 (1962).

<sup>2</sup> 90 Stat. 539, 581 (1976).

<sup>3</sup> 94 Stat. 1190, 1193 (1980).

<sup>4</sup> 111 Stat. 2296, 2375-2376 (1997).

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).<sup>5</sup> 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.<sup>6</sup> Sections 701(a) and 701(b) only help if another section of the Act authorizes FDA access to company records. There are only three limited situations where Congress has provided for food records inspection and one for cosmetics.

In 1938, Congress included limited records inspection authority under Section 703 of the FD&C Act for FDA to document the interstate shipment of food and cosmetics. Section 703 contains detailed requirements and limitations, and is clearly inapplicable to the proposed regulation. If Congress had intended FDA to have broad records inspection authority, Section 703 would have been completely superfluous and meaningless.

Congress has specifically provided, and FDA has exercised, limited records inspection authority under Section 404 of the FD&C Act,<sup>7</sup> and the food industry has not disputed this authority. Section 404 provides FDA with emergency permit authority over food that “may,

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<sup>5</sup> 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.

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

<sup>7</sup> 21 C.F.R. §§ 108.25(g), 108.35(h).

by reason of contamination with microorganisms... be injurious to health,” and authorizes the Agency to attach to each permit “such conditions. . . as may be necessary to protect the public 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.<sup>8</sup> 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.

Similarly, Congress amended the FD&C Act under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002<sup>9</sup> to add (1) a new Section 414(a) specifically to authorize food records inspection where FDA has “a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or

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<sup>8</sup> 21 C.F.R. Parts 113 and 114.

<sup>9</sup> 116 Stat. 594, 662, 669 (2002).

death” and (2) a new Section 801(d)(3)(A)(iv) to authorize records inspection relating to “import for export.” These provisions have no bearing on FDA authority to conduct records inspections other than under the limited circumstances specified in them.

## **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 -- granting FDA its current inspection authority with respect to food and cosmetic manufacturers.<sup>10</sup> 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 FDA Commissioner Charles Crawford 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.

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<sup>10</sup> 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).

Commissioner Crawford stated that FDA inspectors “have been instructed to ask permission to see such records or files whenever there is any need for reason to examine them or to obtain information contained in them,” and observed that:

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.

Thus, the Agency’s contemporaneous interpretation of Section 704 acknowledged that Congress did not grant general records inspection authority to FDA and that the Agency would rely on voluntary industry cooperation.

The current FDA *Investigations Operations Manual* states the same position that the Agency took when Section 704 was enacted in 1953 and has taken in testimony before Congress ever since:

Limitations -- Section 704 of the FD&C Act [21 U.S.C. 374] provides authority for FDA to conduct inspections . . . This section does not include a provision to inspect records within those facilities, except for inspections of prescription drugs, nonprescription drugs intended for human use, and restricted devices . . . or inspections of infant formula . . .<sup>11</sup>

This official current FDA position on the scope of Section 704 directly refutes the position taken in the proposed regulation.

Since 1953, Congress has amended Section 704 to grant records inspection authority for prescription drugs, specified medical 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

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<sup>11</sup> FDA, *Investigations Operations Manual* Section 701.01 (2004).

Congress was aware that the review of records is outside the scope of the general inspection authority provided under the Act.

FDA has testified 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.<sup>12</sup> FDA bears a heavy burden to justify the reversal of its longstanding position, held since the enactment of Section 704 in 1953, that it lacks records inspection authority for food and cosmetics.<sup>13</sup> Rather than meeting this burden, FDA makes no attempt to explain its revised

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<sup>12</sup> *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 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).

<sup>13</sup> *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, (continued...)

interpretation of the FD&C Act. Indeed, the preamble to the proposed and final regulation makes no reference to the Agency's repeated official testimony before Congress that FDA has no records inspection authority for food and cosmetics.

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. The following twelve sections of this Appendix summarize some, but by no means all, of this FDA testimony. 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 message to Congress in March 1962, President Kennedy recognized that the FD&C Act did not provide records inspection for food, drugs, cosmetics, and devices, and recommended legislation to provide this authority.<sup>14</sup> Legislation was promptly introduced by the Administration for this purpose.<sup>15</sup> Following the Thalidomide tragedy, Congress narrowed its focus to drugs.

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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").

<sup>14</sup> H.R. Doc. No. 364, 87th Cong., 2d Sess. 7 (1962).

<sup>15</sup> H.R. 11581, 87th Cong., 2d Sess. (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 then provided under Section 704.<sup>16</sup> The Secretary's written statement and subsequent oral testimony unequivocally demonstrate the Agency's understanding that the factory inspection provisions of Section 704 of the FD&C Act do not include a general authorization for FDA to require access to company records. An exchange between the Chairman of the Committee and Secretary Ribicoff illustrates this point:

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.<sup>17</sup>

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<sup>16</sup> "Drug Industry Act of 1962," *Hearings before the Committee on Interstate and Foreign Commerce, House of Representatives*, 87th Cong., 2nd Sess. 60, 67-68 (1962).

<sup>17</sup> *Id.* at 72.

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.”<sup>18</sup> 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.<sup>19</sup>

Although President Kennedy directly requested that the pending legislation grant FDA authority for records inspection for both nonprescription and prescription drugs,<sup>20</sup> the House<sup>21</sup> and the Senate<sup>22</sup> reports limited this authority to prescription drugs. Ultimately, the expanded inspection authority sought by the Agency at that time for all regulated products was granted by Congress only with respect to prescription drugs.<sup>23</sup>

#### **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, FDA Commissioner Charles Edwards 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

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<sup>18</sup> *Id.*

<sup>19</sup> *Id.* at 73.

<sup>20</sup> *Id.* at 74-75.

<sup>21</sup> H.R. Rep. No. 2464, 87th Cong., 2d Sess. 14, 49 (1962).

<sup>22</sup> S. Rep. No. 1744, 87th Cong., 2d Sess. 13, 31-32 (1962); S. Rep. No. 1744 Part 2, 87th Cong., 2d Sess. 2 (1962).

<sup>23</sup> 76 Stat. 780, 792-793 (1962).

because the Agency lacked the authority to inspect records.<sup>24</sup> 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.<sup>25</sup>

**C. The Cosmetic Safety Act of 1973 and the Food, Drug, and Cosmetic Amendments of 1974**

In 1973, Senator Eagleton introduced the Cosmetic Safety Act of 1973, to provide new FDA enforcement authority for cosmetics.<sup>26</sup> In 1974, the Administration introduced legislation prepared by FDA to expand the Agency's enforcement authority for both food and cosmetics.<sup>27</sup> At a Senate hearing in February 1974 on both bills, FDA Commissioner Alexander M. Schmidt described FDA's limited factory inspection authority for cosmetics:

It is essential that FDA possess sufficient authority to determine the processes through which cosmetics are being

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<sup>24</sup> "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).

<sup>25</sup> *Id.* at 130.

<sup>26</sup> S.863, 93d Cong., 1st Sess.

<sup>27</sup> S.3012, 93d Cong., 2d Sess. (1974).

manufactured. Although FDA's primary source of information in this regard is the factory inspection, our present authority to inspect cosmetic processors is severely limited. An FDA inspector, under our current law, is limited to a visual examination of the processing in a particular establishment. He is not entitled to inspect records of the types I have just discussed, nor can he see shipping records and files showing the source of materials and quality controls.<sup>28</sup>

When the cosmetic bill was reported<sup>29</sup> and subsequently passed by the Senate, it included records inspection authority.<sup>30</sup> The House, however, did not consider the legislation and thus Congress once again determined that cosmetic records inspection authority should not be granted to FDA.

#### **D. The Food, Drug, and Cosmetic Amendments of 1974**

In testimony before the Senate Commerce Committee in September 1974, FDA Deputy Commissioner Sherwin Gardner referred to FDA's "lack of access to the records" of food manufacturers<sup>31</sup> and supported pending legislation that would give FDA the power "to inspect those records in food establishments."<sup>32</sup>

Concerning records inspection authority, we have, again, clear authority under section 404, and no authority under section 402 or under the factory inspection provisions of section 704 of the act.<sup>33</sup>

Congress did not enact the pending legislation that would have granted the authority requested by FDA for both food and cosmetics.

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<sup>28</sup> "Cosmetic Safety Act of 1974," *Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare, United States Senate*, 93d Cong., 2d Sess. 57-58 (1974).

<sup>29</sup> S. Rep. No. 94-1047, 94th Cong., 2d Sess. (1976).

<sup>30</sup> 122 Cong. Rec. 24629 (July 30, 1976).

<sup>31</sup> "Food, Drug, and Cosmetic Amendments of 1974," *Hearing before the Subcommittee for Consumers of the Committee on Commerce, United States Senate*, 93d Cong., 2d Sess. 8 (1974).

<sup>32</sup> *Id.* at 9.

<sup>33</sup> *Id.*

**E. The Consumer Food Act of 1975**

The next year, FDA Commissioner Schmidt again testified in favor of FDA records inspection authority, this time for food under the Consumer Food Act of 1975.<sup>34</sup> In his oral testimony, Dr. Schmidt stated that:

It is essential that our staff possess sufficient authority to determine adequately and accurately the methods by which food is being processed. Our present authority is too limited and we need to be able to inspect pertinent records in plants and have records submitted to us.<sup>35</sup>

In his prepared statement, Dr. Schmidt expanded on this point:

It is essential that FDA possess sufficient authority to determine the manner in which food is being processed. Although FDA's primary source of information in this regard is the factory inspection, present authority to inspect food processors is severely limited. An FDA inspector under our current law is limited to a visual examination of the processing in a particular establishment. He is not entitled to inspect records showing the source of materials, quality controls, or formulation of the products.<sup>36</sup>

The Senate Report on the legislation emphasized that it would “enable FDA to require maintenance of and access to records” and that the “extension of FDA’s inspection authority to these records would reduce the time and cost to the agency.”<sup>37</sup> Nonetheless, this legislation did not progress. Congress once again withheld records inspection authority for food from FDA.

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<sup>34</sup> S. 641, 94th Cong., 1st Sess. (1975).

<sup>35</sup> “Food Safety and Labeling Legislation,” *Joint Hearings before the Subcommittee for Consumers of the Committee of Commerce and the Subcommittee on Health of the Committee on Labor and Public Welfare, United States Senate*, 94th Cong., 1st Sess. 71 (1975).

<sup>36</sup> *Id.* at 85.

<sup>37</sup> S. Rep. No. 94-684, 94th Cong., 2d Sess. 6 (1976).

## **F. The Medical Device Amendments of 1976**

In the Fall of 1973, FDA Commissioner Charles Edwards testified before Senate<sup>38</sup> and House<sup>39</sup> committees that FDA did not have explicit statutory authority to inspect records for medical devices. As a result, Congress amended Section 704 of the FD&C Act in the Medical Device Amendments of 1976 to grant this authority for restricted medical devices, investigational devices, and other specified records,<sup>40</sup> but not for all prescription or nonprescription devices.

## **G. The Food Safety and Nutrition Amendments of 1978**

Three years later, FDA again told Congress that it lacked records inspection authority for food. 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 Food Safety and Nutrition Amendments of 1978.<sup>41</sup> 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**

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<sup>38</sup> "Medical Device Amendments, 1973," *Hearings before the Subcommittee on Health of the Committee on Labor and Public Welfare, United States Senate*, 93d Cong. 1st Sess. 185 (1973).

<sup>39</sup> "Medical Devices," *Hearings before the Subcommittee on Public Health and Environment of the Committee on Interstate and Foreign Commerce, House of Representatives*, 93d Cong., 1st Sess. 155 (1973).

<sup>40</sup> 90 Stat. 539, 581 (1976), Sections 704(a) and (e) of the FD&C Act.

<sup>41</sup> "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).

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.<sup>42</sup> The comments referenced the limitations on the Agency’s inspection authority several times, arguing that “enforcement 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.”<sup>43</sup> 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).<sup>44</sup>

Despite specific consideration of these concerns, however, Congress refused to extend the Agency’s inspection authority to include access to food records.

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<sup>42</sup> *Id.* at 119-131.

<sup>43</sup> *Id.* at 125.

<sup>44</sup> *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.<sup>45</sup>

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.<sup>46</sup>

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

### H. The Drug Regulation Reform Act

In 1978 and 1979, Congress held hearings to consider comprehensive legislation that would have revised all aspects of the FD&C Act relating to the regulation of human drugs. Included in that legislation was a provision granting records inspection authority to FDA for

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<sup>45</sup> *Id.* at 310.

<sup>46</sup> *Id.* at 315-316.

nonprescription drugs.<sup>47</sup> In testimony before the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources in March 1978, Secretary of Health, Education, and Welfare Joseph Califano stated 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.<sup>48</sup>

Three months later, Secretary Califano made the same point in testimony before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce:

And, with respect to inspection power, we have that now with respect to prescription drugs; we do not have it with respect to over-the-counter drugs.<sup>49</sup>

FDA Chief Counsel Cooper similarly testified before that House Subcommittee that:

Our inspection authority would also be expanded so that we could reach records relating to possible violations involving over-the-counter drugs.<sup>50</sup>

His prepared statement expanded on this position:

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<sup>47</sup> S. 2755, 95th Cong., 2d Sess. (1978), "Drug Reform Act of 1978," *Hearings before the Subcommittee on Health and Scientific Research of the Committee on Human Resources, United States Senate*, 95th Cong., 2d Sess. H.R. 11611 and 12980, 95th Cong., 2d Sess. 182 (1978); H.R. 11611 and H.R. 12980, 95th Cong., 2d Sess. (1978), "Drug Regulation Reform Act of 1978, Part 1," *Hearings before the Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, House of Representatives*, 95th Cong., 2d Sess. 4, 185, 513 (1978).

<sup>48</sup> "Drug Regulation Reform Act of 1978," note 47 *supra* at 244.

<sup>49</sup> "Drug Regulation Reform Act of 1978, Part 2," *Hearings before the Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, House of Representatives*, 95th Cong., 2d Sess. 1002 (1978).

<sup>50</sup> *Id.* at 1405.

Also under current law, FDA may inspect records relating to the manufacturer of prescription drugs, but not records relating to over-the-counter drugs.<sup>51</sup>

Thus, in their testimony, FDA representatives adhered to the Agency's longstanding position that the general inspection authority of Section 704 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.

This legislation was not enacted, however, and Congress once again declined to provide FDA with the requested statutory authority.

#### **I. The Infant Formula Act of 1980**

When asked during a 1979 House hearing on the safety of infant formula products why FDA did not have specific company records relating to the matter, FDA Commissioner Jere Goyan replied that:

Our agency has long sought to obtain access to food manufacturers' records and reports. Last year in the House bill, H.R. 13967, there was such a power proposed to be granted to us, but that bill never became law.<sup>52</sup>

The House Report<sup>53</sup> on the Infant Formula Act of 1980 described the need for records inspection for infant formula, and the statute amended Section 704 to grant that power to FDA.<sup>54</sup> It did not, however, grant that power to FDA for other food products.

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<sup>51</sup> *Id.* at 1414.

<sup>52</sup> "Infant Formula," *Hearing before the Subcommittee on Oversight and Investigations of the Committee on Interstate and Foreign Commerce, House of Representatives, 96th Cong., 1st Sess. 60 (1979).*

<sup>53</sup> H.R. Rep. No. 96-936, 96th Cong., 2d Sess. 3, 5, 9-11 (1980).

<sup>54</sup> 94 Stat. 1190, 1193 (1980), Section 704(a)(3) of the FD&C Act.

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

Testimony by FDA officials, including FDA Commissioner David Kessler, in 1991 reflects the Agency's continued recognition that it does not possess the statutory authority to require food and cosmetic manufacturers to disclose their records. In testimony before the Senate Committee on Labor and Human Resources in March 1991, Commissioner Kessler stated that Congress and the Agency "need to look at enhancing our inspection authority, including records inspection."<sup>55</sup> 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 orange juice comes out at night and you can't go and inspect records, it really ties the hands of the field.<sup>56</sup>

In response to a written question, he replied that the FD&C Act "does not authorize FDA access to safety testing data."<sup>57</sup> A week later, in testimony before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce he again referred to the need for "adequate tools such as records inspection" and said that "the statute in the food area does not have records inspection."<sup>58</sup>

In a subsequent hearing before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce in July 1991, Commissioner Kessler also

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<sup>55</sup> "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).

<sup>56</sup> *Id.* at 21.

<sup>57</sup> *Id.* at 122.

<sup>58</sup> "Food and Drug Administration Oversight," *Hearings before the Subcommittee on Health and the Environment of the Committee on Energy and Commerce, House of Representatives*, 102d Cong., 1st Sess. 7, 22 (1991).

explicitly acknowledged FDA's lack of records inspection authority under the Act. The bill under consideration would have amended Section 704 to broaden FDA's general inspection authority to include, among other things, the inspection of records.<sup>59</sup> 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?<sup>60</sup>

Commissioner Kessler agreed with this characterization of the Agency's food inspection authority.<sup>61</sup>

During this testimony, Commissioner Kessler was quite candid regarding the absence of statutory authority to conduct records inspection for food. Commissioner Kessler explicitly recognized that "This legislation would provide the ability to inspect records in the food area, as we have in other areas."<sup>62</sup>

In September 1991, Commissioner Kessler appeared before the Subcommittee on Investigations and Oversight of the House Committee on Energy and Commerce:

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<sup>59</sup> H.R. 2597, 102d Cong., 1st Sess. (1991), "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. 3, 13-14 (1991).*

<sup>60</sup> *Id.* at 77.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 86.

Mr. Dingell. Now in the draft testimony prepared by the FDA for presentation by you on July 17 of this year before Chairman Waxman's committee, a number of legislative recommendations were contained.

The first was the need for FDA to obtain the authority to inspect records at food, cosmetic, and over-the-counter drug establishments to determine if the public health is endangered.

\* \* \*

Mr. Kessler. Mr. Chairman, I'm not wasting any time. I am not waiting. \*\*\*

I assure you, Mr. Chairman, that we're not waiting for new legislation to enforce the law, to be able to protect the public. We are doing everything possible now.

\* \* \*

We can enforce the law. We can get to the result we need. It may not necessarily be the most efficient way, but we can do an awful lot, and that's what I'm pledged to do.<sup>63</sup>

The 1991 legislation that would have expanded the Agency's inspection authority for food and cosmetics was reported out of the House Committee on Energy and Commerce<sup>64</sup> but was not passed by Congress. Thus, the Agency today remains as it has for over 50 years -- without records inspection authority for food and cosmetics.

#### **K. The Food and Drug Administration Modernization Act of 1997**

In testimony on the legislation that ultimately became the Food and Drug Administration Modernization Act of 1997, the prepared statement of FDA Deputy Director Michael Friedman noted that the FD&C Act did not give FDA statutory authority to inspect records for nonprescription drugs, and requested that the law be amended to provide that

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<sup>63</sup> "FDA Management and Enforcement," *Hearing before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, House of Representatives*, 102d Cong. 1st Sess. 144-145 (1991).

<sup>64</sup> H.R. Rep. No. 102-1030, 102d Cong., 2d Sess. 16-17 (1992).

authority.<sup>65</sup> During congressional consideration of the legislation, 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 new FDA authority for records inspection. The nonprescription drug industry accepted this trade-off,<sup>66</sup> and FDAMA accordingly included both provisions.<sup>67</sup> 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,<sup>68</sup> obtained a revised national uniformity provision without records inspection.<sup>69</sup> Accordingly, FDA emerged from this congressional consideration of this matter with another acknowledgement that it has no records inspection authority for food and cosmetics.

**L. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

In the aftermath of the terrorism attacks of September 11, 2001, Congress enacted sweeping new authority for FDA to respond to future acts of terrorism.<sup>70</sup> Recognizing that FDA

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<sup>65</sup> “Reauthorization of the Prescription Drug User Fee Act and FDA Reform,” *Hearing before the Subcommittee on Health and Environment of the Committee on Commerce, House of Representatives*, 105th Cong., 1st Sess. 17, 24 (1997).

<sup>66</sup> FDA, *OTC Industry Gains National Uniformity in Return for FDA Records Inspection*, in FDA, *Enforcement Manual Monthly Bulletin* 3 (February 1998).

<sup>67</sup> Sections 412(a) and (b) of FDAMA, 111 Stat. 2296, 2373-2375 (1997).

<sup>68</sup> 143 Cong. Rec. 17849 ff. (September 5, 1997), 17948 ff. (September 8, 1997), 19579 ff. (September 19, 1997), 19619 ff. (September 23, 1997), 19836 ff. (September 24, 1997).

<sup>69</sup> 143 Cong. Rec. 19876. (September 24, 1997). Section 412(d) of FDAMA, 111 Stat. 2296, 2376 (1997), Section 752 of the FD&C Act.

<sup>70</sup> 116 Stat. 594, 662, 669-670, 676-678 (2002), Sections 414(a) and 801(d)(3)(A)(iv) of the FD&C Act.

has no general statutory authority to require records inspection for food, the Bioterrorism Act of 2002 added Section 414(a) to the FD&C Act to authorize food records inspection under limited emergency conditions -- where FDA “has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death.” It also added Section 801(d)(3)(A)(iv) to the FD&C Act to give FDA access to “import for export” records. The mere enactment of these two provisions is, without more, proof that neither FDA nor Congress believes that the Agency has general statutory power to require records inspection for food. If such authority exists, both Section 414(a) and Section 801(d)(3)(A)(iv) would be redundant and completely unnecessary. Indeed, no such authority was included in the Bioterrorism Act for drugs precisely because the FD&C Act already contains adequate records inspection for these products.

### **III. The Cases Cited by FDA in Support of Prior Records Inspection Proposals Fail to Support the Agency’s Attempt to Reinterpret the Statute.**

The preamble to the proposed regulation merely asserts that FDA has records inspection authority for food and cosmetics but contains no citation to the statutory authority, other than the general rulemaking authority under Section 701(a) of the FD&C Act, and no legal analysis on which FDA relies for inspection of these records. In a preamble to a prior proposed regulation (now withdrawn by FDA<sup>71</sup>), however, the Agency devoted substantial space to arguing that it possesses the legal authority to require the disclosure of food records.<sup>72</sup> In

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<sup>71</sup> 68 Fed. Reg. 19766, 19769 (April 22, 2003).

<sup>72</sup> 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 and cosmetic records.

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 asserted that the 1973 Supreme Court decision in *Weinberger v. Bentex Pharmaceuticals, Inc.*<sup>73</sup> 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.”<sup>74</sup> In *Bentex*, 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.”<sup>75</sup> In the lower court’s view, the judiciary had exclusive jurisdiction to make such determinations.<sup>76</sup> In 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.”<sup>77</sup>

*Bentex* thus rested on an analysis of congressional intent, and its finding of “implicit” authority under general principles governing the primary jurisdiction of administrative

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<sup>73</sup> 412 U.S. 645 (1973).

<sup>74</sup> 61 Fed. Reg. at 3888.

<sup>75</sup> 412 U.S. at 648.

<sup>76</sup> 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 jurisdiction to enforce the requirement that new drugs be cleared as safe and effective before marketing. *Id.* at 648-649.

<sup>77</sup> *Id.* at 652.

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 for food and cosmetics under the FD&C Act, no credible argument can be made that Congress has always intended the Agency's inspection authority to reach these records. FDA's reliance on *Bentex* to claim legal authority to implement the proposed regulation thus is in error.

*National Confectioners Association v. Califano*,<sup>78</sup> 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."<sup>79</sup> 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 said nothing whatever about FDA's authority to inspect those records. FDA did not assert that it had the legal authority to inspect food company records and the court did not so hold.<sup>80</sup>

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<sup>78</sup> 569 F.2d 690 (D.C. Cir. 1978).

<sup>79</sup> *Id.* at 695.

<sup>80</sup> 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."

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, quoted above in sections II(E) and (F) of this Appendix. Since this decision, FDA has continued to seek congressional authorization for records inspection for twenty-five years. 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 for food and cosmetics hampers its enforcement efforts. Nor would Congress have continued to conduct hearings regarding the need for such authority.

Third, *National Confectioners* explicitly rejected Section 701(a) as an independent source of substantive 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."<sup>81</sup>

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 for food and cosmetics, and the Agency's repeated historical acknowledgements that such authority has not been granted, the assertion that FDA may require food manufacturers to disclose these records cannot be sustained.

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<sup>81</sup> *Id.* at 695.

The Agency also cited *Toilet Goods Association v. Gardner*<sup>82</sup> to support its broad assertion that “FDA may impose recordkeeping requirements where they effectuate the act’s goals.”<sup>83</sup> In *Toilet Goods*, however, the Supreme Court did not reach the ultimate issue of whether the FDA regulation was an impermissible exercise of authority.<sup>84</sup> Rather, the Court held that the Toilet Goods Association’s challenge to the regulation was not ripe for judicial review.<sup>85</sup> If FDA believed that *Toilet Goods* provides authority for records inspection for food and cosmetics, the Agency would not have consistently and continually testified before Congress during the 37 years since that decision was handed down that it does not have that authority, would not have repeatedly asked Congress to grant that authority, and would not have stated in the 2004 *FDA Investigations Operations Manual*<sup>86</sup> that it does not have this authority

**IV. Congress’ Refusal to Grant Records Inspection Authority to FDA for Food and Cosmetics 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 concluded in 1938, and confirmed in 1953, that the factory inspection authority in Section 704, together with the interstate shipment records inspection authority in Section 703, is sufficient for effective FDA enforcement of the food and cosmetic provisions of

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<sup>82</sup> 387 U.S. 158 (1967).

<sup>83</sup> 61 Fed. Reg. at 3888.

<sup>84</sup> 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.

<sup>85</sup> *Id.* at 160-161.

<sup>86</sup> Note 11 *supra*.

the FD&C Act. Congress's continued refusal to provide FDA with general 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 cosmetic industries have raised serious concerns regarding the disclosure of records during a warrantless FDA inspection.<sup>87</sup> 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.<sup>88</sup> Subjecting an individual to criminal prosecution without a showing of knowledge or intent is a rare and particularly harsh government action.

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:

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<sup>87</sup> E.g., "Food, Drug, Cosmetic, and Device Enforcement Amendments," note 59 *supra* at 154-167, 168-184, 259-271.

<sup>88</sup> *United States v. Dotterweich*, 320 U.S. 277 (1944); *United States v. Park*, 421 U.S. 658 (1975).

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.

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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 that?

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.<sup>89</sup>

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 issues, 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, FDA has effectively implemented the statute without records inspection authority for food, and since 1938 the Agency has done the same for both food and 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

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<sup>89</sup> "Food, Drug, Cosmetic, and Device Enforcement Amendments," note 59 *supra* at 87.

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. FDA may also obtain records of interstate shipment of food and cosmetics.

FDA Deputy Commissioner for Policy Michael Taylor testified before the Senate Committee on Labor and Human Resources on pending new enforcement legislation in May 1992 that:

Our enforcement record illustrates the general ability to accomplish enforcement objections utilizing current statutory and regulatory authorities.

\* \* \*

The administration continues to believe that increased enforcement authorities are not necessary to protect the public health or safety. Existing authorities are sufficient to accomplish the intent of the food and drug act and related statutes.<sup>90</sup>

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 establishments.

**C. As FDA Has Acknowledged, Food and Cosmetic Manufacturers Routinely Provide Records to FDA Inspectors upon Reasonable Request**

Food and cosmetic manufacturers have long recognized the importance of cooperation with FDA in implementation of the FD&C Act. Whenever any significant issue of public health concern arises, manufacturers respond to any reasonable request for records.

Manufacturers routinely provide records to FDA inspectors on a voluntary basis. FDA

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<sup>90</sup> "Food, Drug, Cosmetic, and Device Enforcement Authorities Act," *Hearing of the Committee on Labor and Human Resources, United States Senate*, 102d Cong., 2d Sess. 6-7 (1992).

Commissioner Charles Crawford acknowledged in the attached FDA press release in August 1953 that this had been true since 1906, FDA Commissioner George Larrick repeated it in 1962,<sup>91</sup> and it remains true today. When Congress granted FDA records inspection authority for nonprescription drugs under FDAMA in 1997, the *FDA Enforcement Manual Monthly Bulletin* reported that:

Inspection Changes Not Significant

The changes in the FDA's approach toward inspection of OTC manufacturers were "not expected to be significant," according to Douglas Ellsworth, director of the FDA's New Jersey District\*\*\*[because] in the past, when investigators have asked to review the records of OTC manufacturers, most firms have allowed this review voluntarily.<sup>92</sup>

This is a primary reason why Congress has determined that it is unnecessary to enact records inspection authority for food and cosmetics.

**D. Enforcement Concerns Cited By the Agency have Been Considered and Rejected By Congress When It Refused to Grant Records Inspection Authority for Food and Cosmetics In the Past.**

FDA implementation of the regulation governing prohibited cattle materials presents no unique issues of law or fact to distinguish it from the cases in which records inspection authority has been requested by FDA and denied by Congress in the past. In the context of enforcement, there is nothing to differentiate compliance with this regulation from any of the other food and cosmetic provisions of the FD&C Act and the implementing regulations promulgated by FDA. If records inspection could be justified here, it could be equally justified

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<sup>91</sup> Note 19 *supra* and accompanying text.

<sup>92</sup> Note 66 *supra*.

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  
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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 result 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”.)