GMP PROPOSAL	CRN COMMENTS
§ 111.70 What requirements apply to packaging and label operations? (a) You must take necessary actions to ensure that each packaging container for holding dietary ingredients or dietary supplements meets specifications so that the condition of the packaging container will not contaminate your dietary ingredients or dietary supplements nor cause them to deteriorate; (b) You must fill, assemble, package, and perform other related operations in a way that protects your dietary ingredients or dietary supplements against adulteration and misbranding. You must do this using any effective means, including but not limited to, the following: (1) Cleaning and sanitizing all filling and packaging equipment, utensils, and dietary ingredient or dietary supplement containers, as appropriate; (2) Protecting manufactured dietary ingredients and dietary supplements from contamination, particularly airborne contamination; (3) Using sanitary handling procedures;	Written procedures must be established and followed to ensure that the correct labels and packaging materials are issued and used. In (a), remove the word "each." Implies that each and every container must be inspected rather than a representative sample.
(4) Establishing physical or spatial separation of packaging and labels from operations on other dietary ingredients and dietary supplements to prevent mixups;	
(5) Identifying, by any effective means, filled dietary ingredient or dietary supplement containers that are set aside and held in unlabeled condition for future label operations, to prevent mixups;	
(6) Identifying the dietary ingredient or dietary supplement with a batch, lot, or control number that can be used to determine the manufacturing history and control of the batch;	
(7) Examining a representative sample of each batch of the packaged and labeled dietary ingredient or dietary supplement to ensure that the dietary ingredient or dietary supplement meets specifications and that the label specified in the master manufacturing record has been applied; and	
(8) Suitably disposing of labels and other packaging for dietary ingredients or dietary supplements that are obsolete or incorrect to ensure that they are not used in any future packaging and label operations.	
(c) You must conduct a material review and make a disposition decision of any packaged and labeled dietary ingredients or dietary supplements that do	

not meet specifications.	
(d) You must only repackage or relabel dietary ingredients or dietary supplements after the quality control unit has approved and documented such repackaging or relabeling.	
(e) You must retest or reexamine any repackaged or relabeled dietary ingredients or dietary supplements. They must meet all specifications and the quality control unit must approve or reject their release for distribution.	
(f) (1) You must control the issuance and use of packaging, and labels and reconciliation of any issuance and use discrepancies; and (2) You must examine, before packaging operations, packaging and labels for each batch of dietary ingredient or dietary supplement to ensure that the label and packaging conform to the master manufacturing record.	
(g) The person that performs the requirements of this section must document at the time of performance that the requirements are performed including, but not limited to, documentation in the batch-production record of: (1) The identity and quantity of the packaging and labels used and reconciliation of any discrepancies between issuance and use; (2) The examination conducted, in accordance with paragraph (b)(7) of this section; (3) The conclusions you reached from retests conducted in accordance with paragraph (e) of this section; and (4) Any material reviews and disposition decisions for packaging and labels.	
(h) You must keep packaging and label operations records required under this section in accordance with § 111.125.	

GMP PROPOSAL	CRN COMMENTS
§ 111.74 What requirements apply to rejected components, dietary ingredients, dietary supplements, packaging, and labels? You must clearly identify, hold, and control under a quarantine system any component, dietary ingredient, dietary supplement, packaging, and label that is rejected and unsuitable for use in manufacturing, packaging, or label operations.	
Subpart F--Holding and Distributing § 111.80 What requirements apply to holding components dietary ingredients, dietary supplements, packaging and labels? (a) You must hold components, dietary ingredients, and dietary supplements under appropriate conditions of temperature, humidity, and light so that the identity, purity, quality, strength, and composition of the components, dietary ingredients, and dietary supplements are not affected.	
(b) You must hold packaging and labels under appropriate conditions of temperature, humidity, and light so that the quality of the packaging and labels are not affected.	
(c) You must hold components, dietary ingredients, dietary supplements, packaging, and labels under conditions that do not lead to the mixup, contamination, or deterioration of components, dietary ingredients, dietary supplements, packaging, and labels.	
Sec. 111.82 What requirements apply to holding in-process material? (a) You must identify and hold in-process material under conditions that will protect them against mixup, contamination, and deterioration	
(b) You must hold in process material under appropriate conditions of temperature, humidity, and light.	
§ 111.83 What requirements apply to holding reserve samples of components, dietary ingredients and dietary supplements? (a) For any reserve samples of components or dietary ingredients you collect, you must hold such reserve samples in a manner that protects against contamination and deterioration: (b) You must hold reserve samples of dietary	

supplements in a manner that protects against contamination and deterioration. This includes, but is not limited to: (1) Holding the reserve samples under conditions of use recommended or suggested in the label of the dietary supplement and, if no conditions of use are recommended or suggested in the label, then under ordinary conditions of use; and (2) Using the same container-closure system in which the dietary supplement is marketed or in one that provides the same level of protection against contamination or deterioration.	
§ 111.85 What requirements apply to returned dietary ingredients or dietary supplements? (a) You must identify and quarantine returned dietary ingredients or dietary supplements until the quality control unit conducts a material review and makes a disposition decision. (b) You must not salvage returned dietary ingredients and dietary supplements, unless: (1) Evidence from their packaging (or, if possible, an inspection of the premises, where the dietary ingredients and dietary supplements were held) indicates that the dietary ingredients and dietary supplements were not subjected to improper storage conditions; and (2) Tests demonstrate that the dietary ingredients or dietary supplements meet all specifications for identity, purity, quality, strength, and composition. (c) You must destroy or suitably dispose of the returned dietary ingredients or dietary supplements if such dietary ingredients or dietary supplements do not meet specifications for identity, purity, quality, strength, and composition, unless the quality control unit conducts a material review and makes a disposition decision to allow reprocessing. (d) If the reason for a dietary ingredient or a dietary supplement being returned implicates associated batches, you must conduct an investigation of your manufacturing processes and those other batches to determine compliance with specifications. (e) You must establish and keep records for this section on the material review and disposition decision and any testing conducted to determine compliance with established specifications in the master manufacturing record for the type of dietary ingredient or dietary supplement that was returned. (f) You must keep returned dietary ingredient and dietary supplement records in accordance with § 111.125.	Restrictions on handling of returns are excessive and more restrictive even than drug GMPs, which distinguish between returns and salvage. Section b says product cannot be salvaged unless it meets all specs, but section c permits reprocessing. Language needs to be clarified to permit appropriate reprocessing. If product is intact and in good condition, it should not be necessary to test for all specifications.

§ 111.90 What requirements apply to distributing dietary ingredients or dietary supplements? Distribution of dietary ingredients and dietary supplements must be under conditions that will protect the dietary ingredients and dietary supplements against contamination and deterioration.	

GMP PROPOSAL	CRN COMMENTS
Subpart G--Consumer Complaints § 111.95 What requirements apply to consumer complaints? (a) A qualified person must review all consumer complaints to determine whether the consumer complaint involves a possible failure of a dietary ingredient or dietary supplement to meet any of its specifications, or any other requirements of this part, including those specifications and other requirements that, if not met, may result in a possible risk of illness or injury. (b) Your quality control unit must review all consumer complaints involving the possible failure of a dietary ingredient or dietary supplement to meet any of its specifications, or any other requirements of this part, including those-specifications and other requirements that, if not met, may result in a possible risk of illness or injury, to determine whether there is a need to investigate the consumer complaint. (c) Your quality control unit must investigate a consumer complaint when there is a reasonable possibility of a relationship between the quality of a dietary supplement and an adverse event. (d) Your quality control unit's investigation of a consumer complaint must include the batch records associated with the dietary ingredient or dietary supplement involved in the consumer complaint. Your quality control unit must extend the investigation to other batches of dietary ingredients or dietary supplements that may have been associated with an adverse event.	ADD: Written procedures must be established and followed for the handling of consumer complaints. Suppliers comments: This section should only apply to manufacturers of dietary supplements whose products are marketed to consumers, not to manufacturers of dietary ingredients whose products are marketed to other companies. Procedures for handling complaints should be uniform. Even if GMP-related complaints are referred to the quality control unit, they should be handled in a manner consistent with the handling of other complaints.
(e) You must make and keep a written record of every consumer complaint that is related to good manufacturing practices. For the purposes of the regulations in this part, a consumer complaint about product quality may or may not include concerns about a possible hazard, to health. However, a consumer complaint does not include an adverse event, illness, or injury related to the safety of a particular dietary ingredient independent of whether the product is produced under good manufacturing practices. The consumer complaint written record must include, but is not limited to, the following: (1) The name and description of the dietary ingredient or dietary supplement; (2) The batch or lot number of the dietary supplement, if available; (3) The name of the complainant, if available;	

(4) The nature of the complaint including how the consumer used the product, (5) The reply to the complainant if any; and (6) Findings of the investigation and follow-up action taken when an investigation is performed. (f)(1) The person who performs the requirements in accordance with this section must document at the time of performance that the requirement was performed. (2) You must keep consumer complaint records in accordance with § 111.125.	

GMP PROPOSAL	CRN COMMENTS
Subpart H--Records and Recordkeeping § 111.125 What requirements apply to recordkeeping? (a) You must keep written records required by this part for 3 years beyond the date of manufacture of the last batch of dietary ingredients or dietary supplements associated with those records.	
(b) Records required under this part must be kept as original records, as true copies (such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records), or as electronic records. If you use reduction techniques, such as microfilming, you must make suitable reader and photocopying equipment readily available to FDA. All electronic records must comply with part 11 of this chapter.	
(c) You must have all records required under this part, or copies of such records, readily available during the retention period for authorized inspection and copying by FDA when requested.	See CRN's separate comments on access to records, referencing an extensive analysis prepared by CRN legal counsel Peter Hutt of the firm of Covington & Burling. FDA has no legal right of access to records relating to regulatory compliance with respect to foods generally, including dietary supplements, except to the limited extent specifically authorized under the recently-enacted Bioterrorism Act. Most companies as a matter of policy do not deny inspectors access to records, but the actual requirements of the regulations should be consistent with the law.

Council for Responsible Nutrition

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August 11, 2003

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

RE: DOCKET NO. 96N-0417, GOOD MANUFACTURING PRACTICES FOR DIETARY SUPPLEMENTS

TOPIC: LEGAL ISSUES

This is the fifth in a series of comments submitted by the Council for Responsible Nutrition regarding the above-mentioned proposed rule. This comment will address legal issues regarding the above-mentioned proposed rule. CRN is in support of strong, realistic GMPs, but we disagree in some important respects with FDA's proposal and we question the legality of some aspects of the proposal as published.

The specific topics included in this set of comments are as follows:

On this same date, CRN is submitting separate comments on the purpose and scope of the rule and on the core issue of process control. In addition, we will submit a separate comment summarizing our section-by-section recommendations. At a later date, but before September 9, we will submit comments on the economic impact of the proposed rule. CRN has requested and been granted this additional time for submission of economic data based on new information we have just obtained pursuant to a FOIA request for underlying data not previously included in the administrative record, relating to FDA's assumptions and calculations on the estimated economic impact of the rule. The first comment in this series (July 8, 2003) provided a four-way

comparison of the proposed GMP with current food GMPs, the industry draft published as the ANPR in 1997, and current drug GMPs.

The Council for Responsible Nutrition (CRN) is one of the leading trade associations representing the dietary supplement industry. CRN has been a strong supporter of Good Manufacturing Practices (GMPs) over the years, and we have an active Regulatory Affairs Committee composed of industry experts in dietary supplement regulation and in the technical aspects of production processes, including GMPs. CRN's member company experts in this arena drafted the guidelines for nutritional supplement manufacturing practices adopted by USP over a decade ago and also prepared the industry draft GMPs submitted to FDA in November 1995 by CRN, joined by other industry trade associations. FDA published the industry draft verbatim in the ANPR on dietary supplement GMPs in 1997.

REQUIREMENT FOR MODELING ON FOOD GMP REGULATIONS

The Dietary Supplement Health and Education Act (DSHEA) authorized FDA to establish GMPs for dietary supplements "modeled after" food GMP regulations. The intent of this Congressional instruction was to avoid a drug-like approach to dietary supplement GMPs and to direct FDA's attention to the more general and flexible nature of food GMPs as a model. Unfortunately, the FDA proposal is highly prescriptive and in some respects even more restrictive that drug GMPs, let alone food GMPs. For example, food GMP regulations, including category-specific food GMPs, permit reliance on Certificates of Analysis for key ingredient or product specifications. Drug GMPs also refer specifically to permissible reliance on Certificates of Analysis, provided the reliability of the supplier has been verified. Yet the FDA proposal on dietary supplement GMPs asserts that such reliance is not acceptable.

The industry draft GMPs submitted to FDA in 1995 by CRN and other trade associations was ultimately published in the ANPR in 1997. That draft was modeled after food GMPs but also included additional provisions based on actual manufacturing practices considered by the industry to represent responsible quality assurance. Among those additional provisions were requirements for written procedures and an elaboration of the appropriate role for a strong quality control unit or function.

FDA's proposed rule adopts a quite different approach characterized by exhaustive finished-product testing rather than a reliance on process control. In our view, the FDA approach is not modeled after food GMPs or after sound quality assurance practices or theory. Some commentors believe the FDA proposal is modeled too closely on drug GMPs, but in fact the agency's approach in some instances goes beyond even drug GMPs, as illustrated above.

In determining whether FDA's proposal is "modeled after" food GMP regulations, it is not sufficient or even relevant to consider those sections of the proposal that are virtually identical to food GMPs. In all category-specific food GMPs, the basic provisions of food GMPs relating to sanitation, for example, are taken as given. In most cases, the category-specific food GMPs go into detail only with respect to unique requirements for the product category, and simply cross-reference the general food GMPs with respect to other basic provisions. In this proposed rule on dietary supplement GMPs, what is relevant is not whether FDA has included some of the basic

food GMP provisions, but whether the agency has relied on other food models in developing the unique requirements applicable to dietary supplements.

The proposed rule not only requires the use of scientifically valid analytical methods in evaluating compliance with specifications, but would require those methods to be "validated," a term most commonly used in drug regulation. The calibration requirements and the provisions relating to electronic and automated records are also closely tied to current drug regulatory policy. The proposed rule fails to include a provision for expiration dating because the agency believes there is not a sufficient level of scientifically valid information to support rigorous expiration dating -- an indication that FDA has in mind the kind and extent of support required in drug labeling, not the level of support that would typically justify shelf life dating for foods.

CRN does not believe the current FDA proposal is sufficiently modeled after food GMP regulations to meet the statutory requirement included by Congress in DSHEA.

GENERALLY AVAILABLE ANALYTICAL METHODOLOGY

DSHEA specifies that any GMP regulations prescribed by the agency "may not impose standards for which there is no current and generally available analytical methodology." The proposed rule requires that "scientifically valid" tests be used in testing for specifications, and section 111.60 requires that these tests must not only be scientifically valid but must be "validated." Given the substantial ongoing efforts directed toward methods development, the agency's requirements would in fact for many ingredients and products impose standards which cannot be met through current and generally available analytical methodology.

In the preamble, the agency says it is "not aware of a situation where an appropriate scientifically valid analytical method is not available," and FDA's economic analysis does not address costs of methods development. Yet at the same time the agency set forth alternatives to finished product testing in cases where adequate methodologies are not available for the finished product, and FDA declined to include provisions relating to expiration dating because the agency says there may not be adequate methods available for assessing the strength of a dietary ingredient.

Industry members have been deeply involved for almost two decades in numerous efforts to develop valid methods for many ingredients, including the longstanding efforts of USP. Industry members have also supported an independent Method Validation Program (INA/MVP) that has finalized a number of analytical methods and has now been incorporated into the NSF International third-party certification initiative. The NIH Office of Dietary Supplements (ODS) recently received special funding by Congress for the development of analytical methods, and AOAC is working with ODS on this project. These ongoing activities in our view are testimony to the fact that there is still a very significant need for methods development that will continue into the future. It is clear that there are numerous ingredients and products for which "there is no current and generally available analytical methodology" that would meet FDA's required standard for tests necessary to confirm compliance with quality specifications.

STATUTORY SCOPE OF AUTHORIZED GMPs

The language of DSHEA authorizes FDA to "prescribe good manufacturing practices for dietary supplements." The term "dietary ingredients" is not mentioned in this context, and Congress did not intend for the dietary supplement GMPs to be so broad as to encompass myriads of food ingredient manufacturers, many of which are also suppliers of "dietary ingredients" to our industry. To the extent that FDA's proposed rule purports to cover manufacturers of dietary ingredients as well as manufacturers of dietary supplements, it is not authorized by DSHEA. Such coverage would be undesirably broad, as it would encompass manufacturers of ingredients widely used in conventional foods and in specialty foods such as functional foods, medical foods, and infant formula, as well as in dietary supplements.

Other GMP regulations applicable to specific food categories, including low-acid canned foods and acidified foods as well as the proposed infant formula GMPs, apply only to manufacturers of the finished products and not to ingredient suppliers. Even drug GMP regulations apply only to manufacturers of finished pharmaceutical products, with suppliers of active pharmaceutical ingredients being covered by a separate FDA guidance document. As discussed in separate CRN comments on the purpose and scope of the rule, this GMP regulation on dietary supplements should, like the food and drug examples mentioned above, apply only to manufacturers of finished products. DSHEA does not permit a broader construction.

There is of course continuing concern in all segments of the industry regarding the best way to assure the quality of dietary ingredients as well as finished products. CRN believes this can be accomplished most effectively by making the finished-product manufacturers responsible for overall quality, since they not only have control over all aspects of processing, but also have control over the selection of ingredients they choose to use in their dietary supplements and are in a position to judge the reliability of suppliers of those ingredients. Thus, making the GMP rule applicable only to finished product manufacturers would conform to DSHEA and would still provide effective control over the quality of dietary ingredients used in the products.

FDA DOES NOT HAVE LEGAL AUTHORITY TO REQUIRE ACCESS TO RECORDS

CRN's member companies are leaders in the dietary supplement industry and have historically sought a cooperative relationship with FDA and with state regulatory authorities. When visited by inspectors, CRN member companies as a matter of corporate policy tend to make every effort to facilitate the inspection, and this often extends to voluntarily showing inspectors written records they may request.

FDA proposes in the GMP rule to require in section 111.125 that records kept in accordance with these GMPs must be "readily available during the retention period for authorized inspection and copying by FDA when requested." Regardless of our member companies' internal policies that may favor voluntarily permitting record inspection, the requirements of the GMP rule must not go beyond those permissible under the FD&C Act.

CRN's legal counsel Peter Barton Hutt of the firm of Covington & Burling advises that "FDA has no statutory authority to require Agency inspection of company records relating to compliance of food with the Federal Food, Drug, and Cosmetic Act (FD&C Act) except under the limited emergency circumstances established by the recently-enacted Public Health Security and Bioterrorism Preparedness and Response Act of 2002." Attached is Mr. Hutt's detailed analysis of the legal issues surrounding FDA access to records applicable to food (including dietary supplements).

In accordance with this legal analysis, CRN concludes that the final subparagraph (c) of proposed section 111.125 must be omitted from any final rule on GMPs for dietary supplements.

NEED FOR PUBLIC HEARING ON THE GMP PROPOSAL

Because of the serious concerns raised by numerous commentors regarding the appropriateness and legality of the FDA proposed rule on dietary supplement GMPs, CRN urges the agency to convene a public hearing or perhaps a series of public workshops on the issues involved in this important undertaking, in order to craft a more workable solution

Sincerely,

A Dickinson

Annette Dickinson, Ph.D.
President

ATTACHMENT TO COMMENTS
SUBMITTED BY COUNCIL FOR RESPONSIBLE NUTRITION:

LEGAL ANALYSIS PREPARED BY CRN COUNSEL
PETER BARTON HUTT OF THE FIRM OF COVINGTON & BURLING

AUGUST 11, 2003

DOCKET No. 96N-0417, GMPs FOR DIETARY SUPPLEMENTS

FDA Has No General Authority Under the Federal Food, Drug, and Cosmetic Act to Require Manufacturers of Food (Including Dietary Supplements) 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 with the Federal Food, Drug, and Cosmetic Act (FD&C Act) except under the limited emergency circumstances established by the recently-enacted Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

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

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

The inspection authority granted to FDA by the FD&C Act does not extend to the mandatory examination of records maintained by food manufacturers except under limited emergency conditions discussed in Part I(B) below, which are not relevant to these proposed regulations. Under Section 704(a), the Agency's authority to inspect the factory, warehouse, establishment, or vehicle of a food 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,[1] restricted devices,[2] infant formula[3], and nonprescription drugs[4] -- it specifically amended Section 704(a) to provide FDA with this expanded inspection authority. If FDA already possessed the authority to inspect records under the FD&C Act, no amendment of the Act would have been required and the records inspection provisions relating to prescription drugs, restricted devices, infant formula, and nonprescription drugs, would be superfluous.

The Agency has sought records inspection authority for food establishments from Congress on several occasions. These efforts have been vigorously opposed by industry because of the serious legal and constitutional issues raised and because FDA has adequate enforcement powers without records inspection. Through the testimony of both the Agency and industry representatives, Congress has been able to consider the competing interests involved, and has determined repeatedly that records inspection authority is not warranted for food products.

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

Section 701(a) of the FD&C Act provides that the Agency has the authority to promulgate regulations for the efficient enforcement of the FD&C Act generally and Section 701(b) grants this authority jointly to the Secretary of the Treasury and FDA with respect specifically to Section 801 of the FD&C Act. After 50 years of acknowledging its lack of authority under Section 704 to inspect the records of food manufacturers, FDA cannot now assert

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1 76 Stat. 780 (1962).

2 90 Stat. 539 (1976).

3 94 Stat. 1190 (1980).

4 111 Stat. 2296 (1997).

that it possesses this authority under Sections 701(a) and 701(b).[5] Sections 701(a) and 701(b) only authorize FDA to issue regulations implementing other substantive provisions of the Act. They do not permit FDA to contravene congressional intent by imposing regulatory requirements exceeding the limited inspection authority provided under the statute.[6] Sections 701(a) and 701(b) only help if another section of the Act authorizes FDA access to company records. None does.

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

Under Section 404(c), Congress explicitly granted FDA the authority to inspect any food establishment "for the purpose of ascertaining whether or not the conditions of the permit are being complied with." This authority is in addition to the general inspection authority under Section 704, and thus was clearly intended by Congress to extend beyond the limited

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

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

7 21 C.F.R. §§ 108.25(g), 108.35(h).

8 21 C.F.R. Parts 113 and 114.

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 Scruity and Bioterrorism Preparedness and Response Act of 2002[9] to add 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 death." Section 414(a) is not cited by FDA as authority for the proposed dietary supplement GMP regulations and has no bearing on the Agency's authority to conduct records inspections other than under the limited circumstances specified in that provision.

FDA HAS REPEATEDLY ACKNOWLEDGED THAT IT LACKS THE AUTHORITY TO INSPECT FOOD 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 manufacturers to disclose their records during an inspection. In 1953, Congress enacted the present factory inspection provision of the FD&C Act -- Section 704(a) -- granting FDA its current inspection authority with respect to food manufacturers.[10] Although FDA had sought statutory authority to

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[9] 116 Stat. 594, 662, 669 (2002).

[10] 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).

inspect all pertinent records relating to food production, Congress withheld such authority from the Agency.

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

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

FDA has gone before Congress several times since the original enactment of Section 704 seeking expanded inspection authority under the Act. In making these appeals, the Agency consistently has maintained that it lacks the statutory authority to inspect food 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.[11] 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.[12] Rather than meeting this burden, FDA makes no attempt to explain its revised interpretation of the FD&C Act. Indeed, the preamble to the proposed and final regulation makes no reference to the Agency's repeated statements before Congress and others that FDA has no records inspection authority for food.

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 records. Over the past five decades, Congress has relied on this testimony in making its legislative determinations relating to the Agency. FDA cannot now usurp Congress's power by attempting to reinterpret the statute at this late date.

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[11] *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).

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

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

In a hearing before the House Committee on Interstate and Foreign Commerce relating to the Drug Industry Act of 1962, Abraham Ribicoff, the Secretary of the Department of Health, Education, and Welfare, and George Larrick, the Commissioner of Food and Drugs, testified regarding the scope of the inspection authority provided under Section 704(a).[13] This testimony and the FDA's written statements unequivocally demonstrate the Agency's understanding that the general factory inspection provisions of Section 704(a) 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.

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

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

SECRETARY RIBICOFF: I would say that we cannot do a good job with these restrictions.[14]

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."[15] 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.[16] 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.

The 1971 Hearings Relating To FDA Oversight/Food Inspection

In 1971, the Agency again sought expansion of its existing food inspection authority from Congress. In hearings before the Subcommittee on Public Health and Environment of the House Committee on Interstate and Foreign Commerce, Charles Edwards, the Commissioner of Food and Drugs, and Virgil Wodicka, the Director of the FDA Bureau of Foods, argued that the Agency's efforts to monitor the quality control systems of food manufacturers were hampered because the Agency lacked the authority to inspect records.[17] In his testimony, Dr. Wodicka explicitly acknowledged that Congress had repeatedly withheld the authority to inspect food records from the Agency:

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14 *Id.* at 72.

15 *Id.*

16 *Id* at 73.

17 "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).

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

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

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

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

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

DR. WODICKA: Yes, sir.[18]

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

Seven years later, FDA again told Congress that it lacked records inspection authority for foods. In 1978, hearings were held before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce with respect to the Food Safety and Nutrition Amendments of 1978.[19] 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.

Comments of the Department of Health, Education, and Welfare

Julius Richmond, the Assistant Secretary for Health, submitted comments reflecting "the general policy views of the Department" as an appendix to his prepared statement

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[18] *Id.* at 130.

before the Subcommittee.[20] 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."[21] 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).[22]

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

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19 "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).

20 *Id.* at 119-131.

21 *Id.* at 125.

22 *Id.* at 128-129.

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.[23]

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.[24]

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

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

In hearings before the House of Representatives and the Senate in 1978 and 1979 relating to the Drug Regulation Reform Act, FDA continued to seek expanded factory inspection authority under Section 704(a). FDA Commissioner Donald Kennedy sought increased

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23 Id. at 310.

24 *Id.* at 315-316.

inspection authority with respect to nonprescription drugs,[25] for which Section 704(a) at that time provided the identical authority as food. In their testimony, FDA representatives adhered to the Agency's longstanding position that the general inspection authority of Section 704(a) does not extend to records inspection. They acknowledged that records inspection is authorized only where Congress has specifically granted FDA broadened authority, as with prescription drugs.

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

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25 *E.g.*, "Drug Regulation Reform Act of 1979," *Hearings Before the Subcommittee on Health and Scientific Research of the Committee on Labor and Human Resources, United States Senate,* 96th Cong., 1st Sess. 361 (1979) ("We think enforcement provisions of the law should be made fairer and more effective by . . . expanding FDA's inspection authority, . . . so that FDA can better develop the facts needed to prove criminal and other violations when they occur."); "Drug Regulation Reform Act of 1978, Part 2," *Hearings Before the Committee on Interstate and Foreign Commerce, House of Representatives*, 95th Cong., 2nd Sess. 1405 (1978) ("Our inspection authority would also be expanded so that we could reach records relating to possible violations involving over-the-counter drugs.").

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

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

nonprescription (OTC) drug manufacturers as well."[28] Congress once again declined to provide FDA with the requested statutory authority.

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

Testimony by FDA officials, including FDA Commissioner Kessler, in 1991 reflects the Agency's continued recognition that it does not possess the statutory authority to require food manufacturers to disclose their records. In testimony before the Senate Committee on Labor and Human Resources in 1991, Commissioner Kessler stated that Congress and the Agency "need to look at enhancing our inspection authority, including records inspection."[29] 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 its'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.[30]

In a hearing before the Subcommittee on Health and the Environment of the House Committee on Energy and Commerce, Commissioner Kessler also explicitly acknowledged FDA's lack of records inspection authority under the Act. The bill under consideration would have amended Section 704(a) to broaden FDA's general inspection authority to include, among other things, the inspection of records.[31] Referencing a report by the

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28 *Id.*

29 "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).

30 *Id.* at 21.

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

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?[32]

Commissioner Kessler agreed with this characterization of the Agency's food inspection authority, replying: "It certainly creates a serious problem."[33]

During this testimony, Commissioner Kessler was quite candid regarding the absence of statutory authority to conduct records inspections for food. Commissioner Kessler explicitly recognized that "This legislation would provide the ability to inspect records in the food area, as we have in other areas."[34]

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

The Food and Drug Administration Modernization Act of 1997

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

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32 *Id.* at 77.

33 *Id.*

34 *Id.* at 86.

accepted this trade-off, and FADAMA accordingly included both provisions.[35] 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,[36] obtained a revised national uniformity provision.[37] Accordingly, FDA emerged from this congressional consideration of this matter with another acknowledgement that it has no records inspection authority for food.

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. Recognizing that FDA 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." The mere enactment of this provision 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, Section 414(a) 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.

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

36 143 Cong. Rec. S8837 ff. (September 5, 1997), S8878 ff. (September 8, 1997), S9133 ff. (September 22, 1997) (daily eds.).

37 143 Cong. Rec. S9145 ff. (September 11, 1997) (daily ed.). Section 412(d) of FADAMA, 111 Stat. 2296, 2376 (1997).

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

The preamble to the proposed regulations merely asserts that FDA has records inspection authority for dietary supplements but contains no legal analysis of the statutory authority on which FDA relies for inspection of food records.[38] In a preamble to a prior proposed regulation (now withdrawn by FDA[39]), however, the Agency devoted substantial space to arguing that it possesses the legal authority to require the disclosure of food records.[40] In particular, the Agency contended that a few older court decisions support its new claim of authority. A review of these cases, however, demonstrates that they are not on point.

The Agency asserts that the 1973 Supreme Court decision in *Weinberger v. Bentex Pharmaceuticals, Inc.*[41] 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."[42] In *Weinberger*, the Court reversed the lower court's holding that FDA lacked jurisdiction under the FD&C Act "to decide in an administrative proceeding what is a 'new drug' for which an NDA is required."[43] In the lower court's view, the judiciary had exclusive jurisdiction to make such determinations.[44] In

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38 68 Fed. Reg. 12158, 12168, 12218 (March 13, 2003).

39 68 Fed. Reg. 19766, 19769 (April 22, 2003).

40 61 Fed. Reg. 3885 (February 2, 1996) (FDA records inspection of nutrient descriptor and disease claims for food). Notably, the preamble did not address FDA's repeated testimony to Congress regarding its lack of inspection authority for food industry records.

41 412 U.S. 645 (1973).

42 61 Fed. Reg. at 3888.

43 412 U.S. at 648.

44 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

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."[45]

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

National Confectioners Association v. Califano,[46] 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."[47] 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.

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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.

45 *Id.* at 652.

46 569 F.2d 690 (D.C. Cir. 1978).

47 *Id.* at 695.

First, and most important, *National Confectioners* applied only to the requirement that food manufacturers make and keep records. It had nothing to say about FDA's authority to inspect those records. FDA did not assert that it could inspect food company records and the court did not so hold.[48]

Second, *National Confectioners* was decided in January 1978. Later that year, FDA made several statements before Congress acknowledging its lack of food records inspection authority under the Act. Since this decision, the Agency has continued to seek congressional authorization for records inspection for more than two decades. If the Agency's authority to inspect records was settled by *National Confectioners*, FDA surely would not have persisted in its testimony to Congress that its lack of records inspection authority in the food area hampers its enforcement efforts. Nor would Congress have continued to conduct hearings regarding the alleged need for such authority.

Third, *National* Confectioners explicitly rejects Section 701(a) as an independent source of authority not found elsewhere in the Act. Emphasizing the importance of congressional intent, the court stated: "Section 701(a) is not a license for expansion of the FDA's regulatory authority based on fanciful interpretations of the substantive portions of the Act."[49]

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[48] 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."

[49] *Id.* at 695.

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

The Agency also cites Toilet *Goods Association v. Gardner*[50] to support its broad assertion that "FDA may impose recordkeeping requirements where they effectuate the act's goals."[51] In *Toilet Goods*, however, the Supreme Court did not reach the ultimate issue of whether the FDA regulation was an impermissible exercise of authority.[52] Rather, as every student of Administrative Law knows, the Court held that the Toilet Goods Association's challenge to the regulation was not ripe for judicial reviews.[53]

The fact that Congress authorized FDA to establish regulations for dietary supplement GMP requirements does not in any way imply that Congress was also authorizing records inspection. GMP regulations and records inspection are, and always have been, entirely

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50 387 U.S. 158 (1967).

51 61 Fed. Reg. at 3888.

52 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.

53 *Id.* at 160-161.

separate and independent powers under the FD&C Act. When both were authorized for prescription drugs in the Drug Amendments of 1962, they were enacted as separate provisions in different sections of the FD&C Act.[54] For 35 years following enactment and implementation of the GMP authority for nonprescription drugs in the Drug Amendments of 1962, FDA never contended that this authorized records inspection and in fact told Congress that it had no such authority[55] -- until that authority was specifically enacted in 1997.[56] And even though the courts have upheld FDA authority to promulgate food GMP regulations, including a requirement for recordkeeping, FDA has never suggested that this inherently authorizes records inspection. Thus, enactment of dietary supplement GMP authority in Section 402(g) of the FD&C Act cannot be interpreted to authorize records inspection.

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

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

Congress's continued refusal to provide FDA with records inspection authority for food has been reasonable and principled. In response to the Agency's efforts to obtain such authority, the food industry has raised serious concerns regarding the disclosure of records during a warrantless FDA inspection.[57] Indeed, granting FDA inspectors the authority to review

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54 Sections 501(a)(2)(B) and 704(a)(1) of the FD&C Act, 76 Stat. 780, 792 (1962).

55 Parts II (D) and (E) of the Appendix.

56 Part II(F) of this Appendix.

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

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.[58] Subjecting an individual to criminal prosecution without a showing of knowledge or intent is a rare and particularly harsh government action. As industry representatives have testified to Congress, the severity of these criminal consequences render the constitutional issues even more compelling and provide a powerful argument against expanding the Agency's inspection authority any further.

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

> MR. HASTERT: . . . The records should be considered the private property of a business. To have people swoop in and take all the records and information that a company has kept to help create a quality product, you all of a sudden create a disincentive to keep records at all. There is a great liability out there.
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[58] *United States v. Dotterweich*, 320 U.S. 277 (1944); *United States v. Park*, 421 U.S. 658 (1975).

> MR. HASTERT: . . . What would prevent somebody from your Agency from coming in, learning the [Coca-Cola] formula, or a formula like that, for instance, that is proprietary information and then several years later, once he has that information and is not in your employ any more, going out and exploiting it?
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> MR. KESSLER: You could go to jail, sir.
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> MR. HASTERT: Even if the individual does go to jail, the secret is already disclosed.
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> 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.
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> MR. HASTERT: People take those risks all the time.[59]

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

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

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

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[59] "Food, Drug, Cosmetic, and Device Enforcement Amendments," note 57, *supra*, at 87.

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.

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

FDA implementation of dietary supplement GMP requirements presents no unique issues of law or fact to distinguish it from the cases in which records inspection authority has been requested and denied by Congress in the past. In the context of enforcement, there is nothing to differentiate compliance with dietary supplement GMP requirements under Section 402(g) of the FD&C Act from any of the other food provisions of the Act. If records inspection could be justified here, it could be equally justified for all other food 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.

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

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

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

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

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

In compliance with other provisions of the new law, inspectors are now giving written receipts for all samples taken in connection with an inspection. District offices of the Food and Drug Administration will report promptly to the management of

food plants the 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".)