Docket No. 02N-0277

BEFORE

THE UNITED STATES OF AMERICA

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

COMMENTS OF THE

AMERICAN HERBAL PRODUCTS ASSOCIATION

ON THE PROPOSED RULE FOR

ESTABLISHMENT AND MAINTENANCE OF RECORDS

AS AUTHORIZED BY

Section 306

of the

Public Health Security and Bioterrorism Preparedness and Response Act of 2002

July 8, 2003

02N-0277

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The American Herbal Products Association ("AHPA") is the national trade association and voice of the herbal products industry, comprised of companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal products. AHPA serves its members by promoting the responsible commerce of products that contain herbs.

Background and Subject of these Comments

The United States Congress passed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act" or "the Act") to improve the ability of the United States to prevent, prepare for, and respond to bioterrorism and other public health emergencies, and President Bush signed this legislation into law on June 12, 2002. The Act consists of five separate titles. AHPA and its members have significant interest in the interpretation and implementation of certain of the statutory requirements established in Title III of the Act (Protecting Safety and Security of Food and Drug Supply).

Section 306 of the Act establishes a requirement for any person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports an article of food to permit, under certain conditions, properly identified officers or employees duly designated by the Secretary of Health and Human Services ("the Secretary") to have access to and to copy all records relating to the manufacture, processing, packing, distribution, receipt, holding, or importation of such article maintained by or on behalf of such person in any format (including paper and electronic formats) and at any location. The conditions for such requirement are defined as:

- the Secretary's reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals; and
- presentation by the Secretary's designated officer or employee to such person at reasonable times and within reasonable limits and in a reasonable manner of appropriate credentials and a written notice.

The Act also authorizes but does not require the Secretary, in consultation and coordination, as appropriate, with other Federal departments and agencies with responsibilities for regulating food safety, to establish by regulation requirements regarding the establishment and maintenance, for not longer than two years, of

records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food, which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The Act specifically requires the Secretary in promulgating any such rulemaking to take into account the size of a business.

The Food and Drug Administration (FDA) published notices of proposed rulemaking in the Federal Register on May 9, 2003 to implement Sections of the Bioterrorism Act, and specifically the rule for the establishment and maintenance of records as authorized under Section 306 of the Act. The notice specified that comments to the proposed rule should be submitted by July 8, 2003.

Most of AHPA's members are companies that either sell bulk herbs or herbal extracts; that manufacture or process herbal ingredients or consumer goods containing herbs, including dietary supplement and food products; or that market consumer goods containing herbs, including dietary supplement and food products. Most of AHPA's members therefore have an interest in the proposed rule.

AHPA submitted initial comments on August 30, 2002, in response to FDA's express request in correspondence dated July 17, 2002, to identify concerns and provide recommended solutions related to the implementation of Section 306 of the Act.

Comments upon proposed rule – overview

AHPA has comments related to a number of specific elements of this proposed rule for the establishment and maintenance of records as authorized under Section 306 of the Act. However, all of the specific comments provided below are submitted with the hope that FDA will reconsider certain of the basic assumptions contained in its proposed rule.

A central feature of the proposed rule is the proposed differentiation between a person defined as a "nontransporter" (and the related "nontransporter immediate previous source" and "nontransporter immediate subsequent recipient") and a person defined as a transporter (and the related "transporter's [or 'transporter'] immediate

previous source" and "transporter's [or 'transporter'] immediate subsequent recipient").

AHPA believes that the person defined in the proposed rule with the "nontransporter" terms is, in fact, the person that Congress intended to identify in subparagraph (a) of this section of the Act. AHPA further believes that the agency's proposal to also define trucking companies, railroads and airplanes by the "transporter" terms, and to place independent recordkeeping requirements on them, is unnecessary and inappropriate. There is nothing in the statute that can be read as authorizing the agency to inspect records of transporters as that authority is granted to FDA only with respect to manufacturers, processors, packers, distributors, receivers, holders, or importers. In any event, both the source and the recipient of each shipment will have a record identifying the transporter. AHPA is aware that there is an inconsistency between subparagraphs (a) and (b) of Section 414 of the Act as amended because subparagraph (b) authorizes but does not require transporters to keep records even though subparagraph (a) does not authorize the agency's access to these records. However, AHPA does not believe that Congress intended transporters like United Parcel Service, the U.S. Postal Service and Federal Express to keep the records that FDA proposes by this rule to have them keep.

Similarly, the plain language of the Act and common usage of the words "source" and "recipient" do not support a requirement that both the source of a food and the recipient of that food maintain records, in every transaction between them, of the entire transportation sequence that moved the goods from source to recipient, for a period of one to two years.

Additional specific comments below will reiterate the points made in this overview. AHPA strongly encourages the agency to reconsider its proposal to create these additional and redundant layers of recordkeeping. If the agency accepts this request, AHPA suggests that the rather clumsy term "nontransporter" be removed from the rule, as the term "person" will suffice absent the need to differentiate between, on the one hand, those firms engaged in the types of activities clearly described by the Act and, on the other, the transportation industry.

Comments to proposed rule – specific comments

AHPA is providing the following comments to specific proposed rules to implement Section 306 of the Act.

1. §§1.327(a) and 1.328: The Act specifically exempts farms from both the record inspection and recordkeeping requirements of this Section 306. The proposed rule appears to implement these exemptions by stating in §1.327(a) that farms are excluded from all of the regulations in this subpart.

   In the definition of "farm" proposed in §1.328, however, the agency has proposed to limit that exemption by defining farms such that all food used in activities related to manufacturing/processing food on a farm would be required to be consumed on that farm or another farm under the same ownership. The proposed definition for "manufacturing/processing," also proposed in §1.328, includes, "...preparing ...food, including food crops [by, for example] ...[c]utting, ... trimming, washing, ...milling, grinding, ...labeling, or packaging."

   A number of AHPA's members are growers who operate farms that specialize in growing herbs that are used as ingredients in dietary supplements. All of these farms cut their crops in order to harvest them, and also trim, wash, label and package their raw agricultural products as part of their common agricultural practices. These are activities that most farms engage in. Several of our farm members also mill or grind their harvests in order to meet market demands for raw agricultural products in cut or powdered forms.

   AHPA believes that the proposed definition of "farm" should be modified to include certain of the defined manufacturing/processing activities, whether these are consumed on that farm or one with common ownership or are offered for sale elsewhere, at least insofar as these activities are related to raw agricultural commodities. The specific manufacturing/processing activities that should be allowed on a farm without voiding the statutory exemptions to Section 306 of the Act granted to farms include at least the following: cutting, at least when this activity is applied to harvest of a farm crop; trimming; washing; labeling, at least when this activity is applied to containers that are not intended for direct consumer purchase; and packaging, at least when this activity is applied to containers that are not intended for direct consumer purchase. The agency should

also consider allowing farms to engage in milling and grinding without voiding the statutory exemption to Section 306 granted to farms, insofar as these activities are common farm activities that most farms engage in.

Finally, AHPA includes among its members a number of companies that produce botanical raw material that is not cultivated but is harvested from wild plants. AHPA is aware that FDA has requested comments, in its proposed rule for prior notice of food imports under Section 307 of the Act, whether the term "grower" includes a harvester or collector of wild products including botanicals. FR 68 at 5437. AHPA has provided comments to that question and stated its belief that harvesters or collectors of wild botanicals can be included in the term "grower" as the term is used in the Act, although harvesters or collectors of wild botanicals do not grow botanicals and should be differentiated from growers for certain purposes.

Consistent with the above identified comment to Section 307 of the Act, AHPA requests that an exemption from the recordkeeping requirements in Section 306 of the Act be clearly established in the final rule for individuals and operations that produce some or all of their botanical raw material by harvesting wild plants, either by including such individuals or firms in the definition of a farm or by some other means. These persons do not manufacture/process or pack foods, and they no more hold foods than does a farmer. It must be assumed that Congress did not intend for these individuals or firms to be considered to be facilities for purposes of recordkeeping under the Act.

2. §§1.327(d)(1) and 1.328: The agency proposes in this paragraph to exempt retail facilities from §1.345, that is, from establishing and maintaining records that identify the immediate subsequent recipients of food sold by retailers.

AHPA supports this exemption for retailers but reiterates here comments made in earlier correspondence on this matter. The proposed definition in §1.328 for the term "retail facility" identifies such a firm as one that sells food products directly to consumers only. The definition includes some examples of retail facilities that are obviously included in such a definition, such as grocery and convenience stores, but it does not include examples of a less obvious nature. AHPA therefore requests the addition of other examples such as "pharmacies that sell foods, including dietary supplements;" "naturopathic or acupuncture clinics

that sell herbal dietary ingredients;" and "direct-selling distributors in the multi-level sales channel." Each of the examples in the proposed definition and the three suggested above have in common that they are forums in which retail sales are made in person. By definition, retail sales made by mail-order or on the internet are retail sales negotiated by mail or electronically rather than in person. Examples of retail facilities that do not use an in-person format should also be included in this definition.

While the proposed rule plainly intends to exempt all such retailers from the requirements of §1.345, the proposed definition of the term "retail facility" is not sufficiently inclusive to assure that there is no confusion related to these less obvious retailers. Several of AHPA's members utilize these channels of trade, and so rely on practitioners such as naturopaths, chiropractors, acupuncturists and others or on individual direct distributors to actually sell and deliver their dietary supplement and food products to the consumer, or provide their goods directly to consumers by mail order or via internet sales. AHPA requests that this definition be clarified by including some or all of these less common examples.

3. §§1.328 and 1.362: The Act specifies that Section 306 shall not be construed to extend to recipes for food, among other things.

Consistent with this explicit Congressional language, the proposed rule at §1.362 states that these recordkeeping requirements do not extend to recipes for food, among other things. Nevertheless, the agency offers a definition of "recipe" in §1.328 of the proposed rule, as follows:

> *Recipe* means the quantitative formula used in the manufacture of the food product, but not the identity of the individual ingredients of the food.

AHPA assumes that FDA has proposed this definition to clarify its view of the limitation of the statutory exclusion and in fact the agency, in discussing this definition in the preamble to the proposed rule, identifies its need to access records for the ingredients of a food. FR 68 at 25195. While this is a logical point and may be consistent with the intention of the Act, AHPA finds the proposed definition as written to be, at best, confusing and potentially perceived as nearly nonsensical. AHPA suggests that this definition be removed and that instead §1.362 be modified to add, for example, "Notwithstanding the exclusion of recipes

for food from this subpart, all of the ingredients in a food are subject to this subpart."

4. §1.337(a): As stated in more detail above, the Act requires persons in the food industry to establish, maintain, and provide to the Secretary certain information under certain conditions to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food.

   The proposed rule as stated in the second sentence of §1.337(a) would require nontransporters, and apparently all of them, to include in their records for all foods they receive "reasonably available" information on the specific source of each ingredient in the received food. AHPA opposes this specific sentence of the proposed rule, as it unacceptably seeks to extend responsibility for identifying the source of ingredients beyond the recipient of the ingredients without in any meaningful way furthering the purpose of this part of the Act.

   Section 306 of the Act balances the regulatory need for gaining access to important information about the source and recipient of all foods with the business need to protect information about proprietary sources and to avoid redundant and expensive recordkeeping. This section of the Act is built on the assumption that, if each person in the line of distribution has a record of the immediate source of the foods they receive and the immediate recipient of every food they release, up to the point of retail, a record of the chain of custody for that food will be established and maintained from the farm to the store. In this system the only nontransporter for whom information on the specific source of each ingredient in a food should be "reasonably available" is the person who received those ingredients – most likely then the manufacturer/processor.

   An illustration may be useful, as follows. If ABC Foods is in the business of manufacturing soup, it may obtain ingredients for its soup products from any number of sources, for example, poultry and dairy farms; vegetable growers; pasta manufacturers; etc. Under proposed §1.337(a)(1)-(6) ABC Foods would be required, consistent with the Act, to establish and maintain all of the records described in these subparagraphs for all of the ingredients that go into their soups. If ABC then sells pallet lots of their soups to the XYZ Food Distributors, for example, who then sells case lots to 123 Markets, the language in the identified sentence of 1.337(a) of the proposed rule would require both XYX and 123 to

include in their records information "reasonably available" to them to identify the specific source of each ingredient in the soup. But none of this information is reasonably available to these vendors, so the agency has identified a rule that no person other than the processor / manufacturer can keep, and for the processor / manufacturer, this sentence is redundant to all of the following subparagraphs (i.e., §1.337(a)(1)-(6)). AHPA suggests that the sentence be deleted.

AHPA is aware of FDA's discussion in the preamble to the proposed rule of the agency's intention to including this sentence as a way of dealing with the fact that the food industry often relies on multiple sources of ingredient to make food products and that it is common practice to comingle ingredients from different sources prior to incorporating them into a finished product. FR 68 at 25196-25197. AHPA supports the intention that guided the agency to propose this language and appreciates the expressed understanding that recordkeeping in such instances may not necessarily identify one specific source of every food ingredient. As illustrated in the example above, however, AHPA does not believe this has been clearly addressed as the proposed language appears to place a burden on all firms that receive a manufactured food to identify "reasonably available" information about the sources of the foods ingredients, when no such information is reasonably available. AHPA suggests that the agency either propose some language that limits the implication of this language to activities up to and including manufacturing / processing (e.g., "...except that packers, distributors, receivers, holders, and importers of manufactured/processed foods are not required to establish or maintain records about the specific sources of any of the ingredients in the manufactured/processed foods that they pack, distribute, receive, hold, or import") or alternately, that the agency clarify this in some other manner.

5. §1.337(a)(4): AHPA objects to that aspect of the proposed regulations which would require it to establish and maintain records which reflect "[t]he lot or code number or other identifier of the food (to the extent this information exists)" for each food it receives, releases, or transports. Although in some cases the lot or code number or other identifier of a food may literally *exist* for the foods AHPA members handle, it is not the case that it is either readily available to AHPA members or economically feasible for AHPA members to track. Moreover, this

aspect of FDA's proposed regulations are not mandated by the language of the Bioterrorism Act and any incremental security benefit that might be provided by such a requirement cannot outweigh the extraordinary burden placed on the distribution system, which will in turn drastically drive up consumer prices and interrupt the smooth functioning of the food supply. When there are food emergencies, retailers do not proceed to remove product from the shelves by lot number. They remove it by brand and type and sort out the details well after their initial response. AHPA requests that this subparagraph be removed.

6. §§1.337(a)(6) and 1.345(a)(6): The proposed rule would require that nontransporters' records for all foods they receive (§1.337(a)(6)) and release (§1.345(a)(6)) include identifying information for the "transporter**s**" (emphasis added) who transported the food.

   AHPA believes it to be reasonable to assume that the person who is the source of a food will have a record of the transporter to whom they release food for delivery to their customer recipient, and that this recipient will have a record of the transporter from whom they receive food from their supplier source. It is not reasonable, however, to assume that either of these persons will have, or to require either of these persons to have, a record of intermediate transporters, if any.

   AHPA therefore requests that these sections specify that identifying information be required only for the delivery firm with whom the source and recipient have direct contact. Thus, §1.337(a)(6) would require, for example, information about "the transporter from whom you received the food," and §1.345(a)(6) would require, for example, information about "the transporter to whom you released the food."

   Of additional concern is the specific information required in these two paragraphs to identify the transporter's "responsible individual," address and, if available, fax number and e-mail address. Many of the dietary supplement products sold by AHPA members are sold in small packages and are shipped in small quantities to individual retailers. Thus, carriers such as United Parcel Service, Federal Express, and the United States Postal Service often transport these food products. Companies that have established accounts with these firms often transact their business through internet connections. Other firms utilize

local, intrastate, and/or interstate trucking firms or airlines and may communicate with the transporter by phone, by email, or again through internet connections. It is AHPA's understanding that use of fax communication between a transporter and a food's source or recipient is probably rare today. Also, the transporter's address is not relevant to transactions between either the source or the recipient of a food.

It is neither necessary nor sensible to require the specific identifying information about a transporter delineated in these proposed paragraphs for each shipment released or received in the process of transacting business. AHPA suggests that these sections be rewritten to require "sufficient identifying information" about the transporter to allow the Secretary, and by extension FDA, to contact the transporter in the event of a credible threat of serious adverse health consequences or death to humans or animals.

7. §§1.351 – 1.352: As stated in the overview comments above, AHPA does not believe it is appropriate or warranted to place a recordkeeping requirement on transportation companies. Aside from the reasons given above, it is also apparent that this part of the proposed rule is redundant and inefficient, such that, in all cases in which the route of transportation between a food vendor and a food buyer consists of a single carrier (e.g., United Parcel Service; Federal Express; US Postal Service; many overland carriers), the transporter will be required to create a third copy of exactly the same information that the seller and the buyer are required to establish and maintain under §1.345 and §1.337, respectively. In addition, some vertically integrated firms own both the shipper (for example, a manufacturer/processor) and the receiver (for example, a packer or distributor) of the food, as well as the vehicle used in the conveyance of the food, so that even more redundant and unnecessary recordkeeping will be required of such firms.

   AHPA strongly encourages the agency to strike §§1.351 – 1.352 in their entirety.

8. §1.361: The Act requires persons in the food industry to permit certain of the Secretary's officers or employees to have access to and copy all records relating to foods under their control when such records are needed to assist the Secretary in determining whether the food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. The Act specifies

that such access is to be at reasonable times and within reasonable limits and in a reasonable manner.

The agency has proposed that the time in which requested records will be required to be made available for inspection will be within 4 hours of a request if the request is made between 8:00 a.m. and 6:00 p.m., Monday through Friday, and within 8 hours of a request made at any other time.

AHPA is concerned with a number of the details included in proposed §1.361. To begin with, the standard business hours for many firms are different hours than from 8:00 a.m. to 6:00 p.m. AHPA suggests that reference to the specific time "between 8:00 a.m. to 6:00 p.m." be replaced with the term, "during times in which a firm is operating," or "during a firm's normal business hours," or other similar statement.

AHPA is also concerned that the meaning of the word "made" as used in relation to a request for information under this paragraph is not clearly defined or that it implies that a request is made as soon as FDA posts a written request in the U.S. Mail, or dials a fax number, or sends an email, for example, with no reference as to whether such request has been received by a firm. AHPA requests that the mandated response times in this paragraph be measured from the time that a request is received by the duly designated employee or officer or other designated employee of the firm.

In addition, although AHPA can not provide specific analyses as to the amount of time necessary to make records identified in this part available for inspection and photocopying, AHPA member companies have communicated their concern that the minimum time of 4 hours is insufficient and that 8 hours is a reasonable period.

AHPA is also concerned that the requirement to provide records within 8 hours of a request made at any time other than 8:00 a.m. and 6:00 p.m., Monday through Friday might imply, unless the agency accepts the above suggestion with regard to measuring the allowed response time from receipt of a request, that all food manufacturers, processors, packers, distributors, receivers, holders, and importers will be required to work at least two shifts per day 7 days per week. By way of illustration, if a request is written and submitted via email just after 6:00

p.m., will a firm need to return already departed staff to fulfill the request by just after 2:00 a.m. the next morning? What if none of the firm's employees receive the request until 9:00 a.m. the next morning – will that constitute a prohibited act under section 301?

Finally, there are companies in the dietary supplement trade that do not manufacture the goods that they sell and so label these goods as "manufactured for" or "distributed by" the company, in conformity with 21 CFR 101.5(c). In some cases these companies do not actually receive goods prior to delivery to their customers as the contracted manufacturer or some other contracted firm serves as the shipping warehouse. In such instances the company that is identified on a product's label will likely therefore have no shipping or receiving records that are relevant to this part, yet it is likely the distributing company identified on the label that would be the one that FDA would contact under this part. AHPA requests that the final rule address this issue and suggests that this could be addressed in §1.361 by adding, for example, a sentence such as, "If the food that is the subject of such request for records and other information is manufactured for you or distributed by you, but is not manufactured by you or received by you, you must forward the request to the company or companies that manufactured or received the food for you within 24 hours of your receipt of the request."

Additional comments

AHPA is concerned that the proposed rule is silent on the Act's specific demand that the Secretary take appropriate measures to ensure that there are in effect effective procedures to prevent the unauthorized disclosure of any trade secret or confidential information that is obtained by the Secretary pursuant to this section. AHPA requests that the agency provide a specific regulation in the final rule that recognizes this statutory requirement. AHPA also urges the agency to consider that companies may consider almost all information about their businesses to be sensitive and confidential as measures are established in the fulfillment of this obligation under the Act and to therefore consider that all information that is not necessary to meet the intended purposes of this section be allowed to be redacted by a firm prior to submitting information to the agency under this section.

In addition and as noted in our preliminary comments on August 30, 2002, AHPA is concerned that the expanded authority for inspection of records defined in this section of the Act could be interpreted more broadly than the Congressional intent in providing this authority. The final rule to implement this section should define the level of evidence or information necessary to rise to the level of "a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death in humans or animals."

AHPA appreciates the opportunity to provide these comments to the proposed rules for registration of food facilities under the Bioterrorism Act and hopes that the agency will treat these comments seriously.

Respectfully submitted,

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