



*Advancing Quality Healthcare
Through Over-the-Counter Medicines
and Nutritional Supplements*

CONSUMER HEALTHCARE PRODUCTS ASSOCIATION

July 7, 2003

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

Submitted electronically to: fdadockets@oc.fda.gov

Re: [Docket No. 02N-0277] Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 25118-25240 (May 9, 2003)

These comments are submitted on behalf of the Consumer Healthcare Products Association¹ in response to the proposed regulations published in the May 9th *Federal Register* Notice. [Docket No. 02N-0277], 68 Fed. Reg. 25118-25240 (May 9, 2003).

The above referenced Notice of Proposed Rulemaking would establish regulations implementing that portion of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act") which mandates the maintenance and inspection of records to permit the FDA to identify the immediate previous sources and the immediate subsequent recipients of food and its packaging through the distribution chain. *See* section 306, Pub. L. No.107-188, codified at 21 U.S.C. § 350c (2002). Such information is intended to allow the agency "to address credible threats of serious adverse health consequences or death to humans or animals" that may be presented by the nation's food supply. *Id.*

In many respects, CHPA does not disagree with the general approach of the FDA's proposed rules. The agency correctly points out the inconsistency between the statutory language of the Bioterrorism Act that permits, on the one hand, that FDA "may by

¹ CHPA, founded in 1881, is the national association representing manufacturers and distributors of over-the-counter (OTC) medicines and nutritional supplements. Its membership comprises over 200 companies across the manufacturing, distribution, research, supply and advertising sectors of the self-care industry.

regulation establish requirements regarding the establishment and maintenance” of such records, (*see* § 306, inserting § 414(b) to the Food, Drug & Cosmetic Act, codified at 21 U.S.C. § 350c(b)) and, on the other hand, the later Congressional command that “the Secretary *shall* promulgate proposed and final regulations enacting recordkeeping requirements . . .” (*id.* at section 414(d) codified at 21 U.S.C. § 350c(d)). However, CHPA agrees with FDA that the rulemaking approach adopted by the agency is indeed justified and will provide needed clarity and predictability to requirements on industry and the expectations of government agents with respect to available records. The Bioterrorism Act mandates that persons who manufacture, process, pack or distribute food shall permit access to all records relating to such articles that are needed “to assist the Secretary in determining whether the food is adulterated. . . .” *Id.* at § 414(a) codified at 21 U.S.C. § 350c(a). These proposed regulations importantly provide, under the discretionary rulemaking authority of FDA, the boundaries and limits for what records shall be provided. Although CHPA takes issue with certain specific aspects of these proposed rules, we view the issuance of these discretionary regulations as a positive step that will provide predictability and make clear the agency’s expectations for compliance.

CHPA also applauds the agency’s foresight to expressly exempt these particular recordkeeping requirements for the immediate prior source and the immediate subsequent recipient from the more general requirements established by Part 11 of Title 21 for electronic records, *see* 68 Fed. Reg. 25198, especially given the agency’s assurance that this proposal should not require duplication of existing records. This will relieve industry of a great deal of unnecessary burden. For similar reasons, CHPA also agrees that outer packaging should not be included in the recordkeeping mandate. (*See* 68 Fed. Reg. 25130.) CHPA believes the agency correctly assesses the low level of risk from outer packaging. Requiring recordkeeping for outer packaging would increase the costs of compliance for industry with very little likelihood of risk in the first place.

However, CHPA seeks clarification concerning FDA’s interpretation of the recordkeeping requirement as applied to packaging manufacturers and distributors. FDA considers the term “food” to include not only articles that are intended to be ingested, but also “substances that migrate into food from food packaging, including immediate food packaging or components of immediate food packaging *that are intended for food use*” 68 Fed. Reg. at 25194 (emphasis added). It is unclear what recordkeeping burdens would be imposed on upstream packaging manufacturers and distributors before those products come into contact with food. CHPA believes that the recordkeeping requirements with respect to the source of immediate packaging should apply only to the person who applies the packaging to the food because upstream manufacturers of the packaging materials do not necessarily *intend* that the material will be used for food – meaning that the person applying the immediate packaging must keep records of all its immediate previous sources of the packaging material, but upstream manufacturers of the packaging material should be relieved of such obligations.

The point at which the immediate packaging is applied should be the beginning of the recordkeeping component for packaging materials. However, CHPA believes this requirement should not extend to the suppliers of the packaging materials *before* those items come in contact with food. Otherwise, these recordkeeping mandates could apply upstream to packaging manufacturers all the way to the wood pulp producers (in the case of paper packaging), the plastic resin manufacturers (in the case of bottles), and the steel producers (in the case of cans and metal tins) who might have an inclination that some of their output may at some point be used in food packaging, but might be manufacturing packaging materials for a myriad of unrelated uses as well. Unlike the items contained by the packaging (i.e., food), which are intended for consumption from the moment they is harvested, producers of packaging materials may have no idea of the specific packaging uses to which their output will be applied.

Secondly, CHPA questions whether persons who merely transport food on behalf of a manufacturer or distributor (but do not take title to the goods) should be included in these recordkeeping requirements at all. Manufacturers and distributors (referred to by FDA in the *Federal Register* Notice as “nontransporters”) will be required keep records of their “transporters,” as well as the immediate prior sources and immediate subsequent recipients prior and the authorization for imposing these burdens on common carriers is less apparent. That means there will exist at least two – and in some cases, three – points of contact for the agency for any food transaction prior to reaching the consumer, and at least two sets of records identifying transporter as well. CHPA notes that the command to grant access to the Secretary to records in section 306 of the Bioterrorism Act (adding §414(a) of the FD&C Act) does not even include the word “transports.”² That reference only appears in subsection 414(b), which permits the Secretary to promulgate regulations with respect to persons who “manufacture, process, pack, **transport**, distribute, receive, hold, or import food.” (emphasis added) *Id.* at §306, adding section 414(b) of the FD&C Act, codified at 21 U.S.C. §350c(b).

If Congress chose not to confer on the Secretary the authority to access records of mere transporters, why then should be Secretary establish regulations demanding recordkeeping by these entities? As pointed out above, there is already there is complete duplication of recordkeeping within every step in the food distribution chain -- each “nontransporter” link in the distribution chain must keep records of both its immediate prior source and its immediate subsequent recipient as well as the entities that transport the food between them. Why then insist that “transporters” also keep this same information and create yet another duplication of efforts to this process? Based on the statutory text and economy of

² “... each person (excluding farms and restaurants) who manufactures, processes, packs, distributes, receives, holds, or imports such article shall . . . permit such officer or employee . . . to have access to and copy all records relating to such article that 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.”, adding § 414(a) of the FD&C Act, codified at 21 U.S.C. § 350c(a) (2002). Note the absence of authority for the Secretary to access records of those who merely “transport” the goods.

commercial resources, CHPA believes this added layer of recordkeeping is unwarranted and therefore unduly burdensome.

Thirdly, CHPA seeks clarification of how direct selling merchants are affected. Several of CHPA's members are direct selling merchants who distribute dietary supplements through a network of at-home consultants. CHPA would appreciate recognition that these merchants are considered "retailers" under the proposed regulations with a specific reference to this category of merchants in the examples of "retail facility" provided. *See* proposed 21 C.F.R. § 1.328. Moreover, CHPA seeks clarification that a direct seller who transfers goods to other direct sellers only within that company's closed system of distribution does not forfeit its status as a retailer. The proposed definition of "retail facility" in § 1.328 would be limited to facilities that "sell food products directly to consumers *only*." *Id.* (emphasis added). However, it is apparent that FDA has not fully considered direct selling operations in its development of the proposal and CHPA hopes that, with a fuller appreciation of this marketing system, FDA will agree that direct sellers are indeed retail facilities deserving of express recognition in the regulations.

CHPA respectfully suggests that the proposed regulations should consider modifying the proposal so that these direct sellers would qualify as "retail facilities." As such, they would keep records of the shipments received from their parent corporation, but not their customer transactions, nor would they be required to keep records of transactions between individual distributors within the closed distribution chain. Moreover, even if one tier of these direct sellers places orders on behalf of, and receives commissions from, its network of distributors, that would not remove the retail exemption from these transactions so long as the product is delivered solely within the closed system to the consumer. CHPA would appreciate clarification of how the proposed rules might apply to this important segment of the dietary supplement industry.

CHPA also questions the "all or nothing" approach to qualifying as a "retail facility." A distributor who sells directly to consumers, but also to other distributors appears to fail to qualify as a "retail facility."³ Therefore, it would be required to keep complete information (including lot numbers of product delivered) for all immediate subsequent recipients, including the consumers with whom it deals. Yet a retail store selling exclusively to consumers would not be required to keep this same information for these transactions. It would seem more appropriate to define the nature of the retail exemption by looking at the purchaser in the transaction (and inquiring whether the transaction is for personal use or food service use as opposed to additional subsequent distribution), rather than establishing a blanket rule that denies some distributors of the exemption for purposes of all of their transactions merely because some of them do not involve the end user of the product.

³ A "retail facility" in proposed § 1.328 is limited to facilities that "sell food products directly to consumers *only*." 68 Fed. Reg. at 25238 (emphasis added).

Lastly, CHPA appreciates the statements clarifying that FDA does not intend to cause reconfiguration of manufacturing facilities in order to establish the specific sources of food ingredients for particular lots. *See* discussion of “commingled ingredients” at 68 Fed. Reg. at 25196. FDA acknowledges that some existing plant configurations rely on multiple sources of ingredients and manufacturers and processors commingle ingredients from these different sources prior to incorporating them into a finished product. If ingredients are commingled and may come from one of several suppliers, having records of all such suppliers would be sufficient under the proposal. CHPA believes this recognition by FDA of typical industry practice and the agency’s efforts to accommodate current manufacturing systems are important to the workability and feasibility of implementing Congress’ mandate and urges that this approach be maintained in the final rule.

CHPA and its members are eager to work with the agency to implement the requirements of the Bioterrorism Act in a manner that assures public health but imposes the least burdens on industry that are needed to carry out the mandates of the law. We appreciate this opportunity to provide our views to the agency on this important topic.

Respectfully submitted,

A handwritten signature in black ink, reading "Steven M. Mister". The signature is written in a cursive style with a large, stylized initial "S".

Steven M. Mister
Vice President & Associate General Counsel