Chocolate Manufacturers Association • National Confectioners Association
7900 Westpark Drive • Suite A-320 • McLean, Virginia 22102-4203
Telephone: 703/790-5011 • Telephone: 703/790-5750
FAX: 703/790-5752

July 8, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Docket No. 02N-0277

Dear Sir or Madam:

The Chocolate Manufacturers Association (CMA) and the National Confectioners Association (NCA) appreciate this opportunity to submit comments regarding the Food and Drug Administration's (FDA) proposed rule on establishment and maintenance of records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). 68 Fed. 25,188 (May 9, 2003).

CMA is the not-for-profit trade association representing the majority of chocolate manufacturers in the United States. In addition to supplying the trade with bulk chocolate products, CMA members also manufacture a wide variety of finished chocolate and chocolate-containing confectionery products for the consumer market. NCA is the not-for-profit trade association representing more than 650 confectionery manufacturers and suppliers in the United States.

CMA and NCA appreciate the need for FDA to be able to quickly reconstruct the chain of custody for any food product the agency reasonably believes poses a risk of serious adverse health consequences or death. However, we have serious concerns about certain aspects of the proposed rule that we believe would impose significant new burdens without improving public health protection. The proposed rule would require maintenance of detailed records regarding the vast majority of commercial food transactions in the United States. In most cases, such records would be required to be retained for two years and made available to FDA inspectors within four hours of a request for production. Noncompliance with these record keeping and records access requirements would be a prohibited act, subjecting a company to civil and criminal liability. In addition, company executives can be held personally criminally liable for such violations. *See United States v. Park*, 421 U.S. 658 (1975); *United States v. Dotterweich*, 320 U.S. 277 (1943).

CMA and NCA urge FDA to exercise this new authority judiciously and to adhere closely to the Bioterrorism Act. To the extent that FDA's purposes can be accomplished using existing

records, this should be done. Moreover, companies should be given a more reasonable amount of time in which to make records available to FDA.

We urge FDA to make the following changes to the proposed rule:

1. The final rule should limit record keeping to the specific information needed by FDA to conduct an efficient tracing investigation.

a. The final rule should delete the requirement to retain the name of a "responsible individual."

Under the proposed rule, whenever records must be retained about another firm (*e.g.*, records regarding the immediate nontransporter previous source of food, the immediate nontransporter subsequent recipient of food, or a transporter of food), the records must include the name of a "responsible individual" at that firm. The proposed rule does not explain who would qualify as a "responsible individual," nor does it state the purpose of requiring this information.

This proposed requirement to retain the name of a responsible individual should be removed from the final rule. This information is not required by the Bioterrorism Act and currently is not uniformly maintained in existing records. Individual employees change on a frequent basis, especially in large companies, and maintaining records with an outdated name potentially could subject a company to criminal penalties. In addition, under the facility registration proposed rule (implementing section 305 of the Bioterrorism Act), FDA will have in its own records the name of an emergency contact person for every registered food facility in the United States and overseas. Since the circumstances in which FDA will be seeking access to records under this proposed rule will, by definition, be emergencies, FDA should be able to obtain the information it needs from a company's emergency contact person. CMA and NCA request that FDA delete this requirement from the final rule. Alternatively, the agency should require the name of a responsible individual or department.

b. The final rule should clarify the requirement to maintain lot-by-lot records matching incoming ingredients to shipped finished products.

Under the proposed rule, a nontransporter must maintain the lot or code number "or other identifier" for each article of food it receives or sends, "to the extent this information exists." In addition, a nontransporter must maintain records matching incoming ingredients to lots of outgoing finished products, to the extent such information is "reasonably available." The proposed rule does not explain what "other identifiers" FDA would consider acceptable, and the proposed rule does not explain when FDA will consider information matching lots of incoming ingredients to lots of finished product to be "reasonably available."

These requirements need to be carefully clarified. The following are some questions that will need to be addressed in the final rule:

- What is a "lot or code number or other identifier"?
- When does a "lot or code number or other identifier" exist, and when does it not exist?
- When are records matching the source of incoming ingredients to lots of finished product considered to be "reasonably available"?

FDA should be aware that many of the raw materials received by confectionery manufacturers do not have lot numbers or similar identifiers. For example, cocoa beans received by manufacturers of chocolate typically arrive in burlap sacks that bear no lot numbers. Immediate food packaging and other food contact substances (*e.g.*, plastic wrap), which are within the definition of "food" under the proposed rule, may not have a lot number or other identifier. The final rule should make clear that a lot number is not required for such foods. The final rule should also clarify that company codes, whether or not denominated as lot numbers, are acceptable identifiers.

CMA and NCA are particularly concerned about the proposed requirement to match lots of incoming ingredients to lots of finished product. Many ingredients used in confectionery products are fungible and commingled (*e.g.*, chocolate liquor, sugar, flour, corn syrup). It is simply not feasible to identify a specific shipment of corn syrup, for example, to a specific lot of finished product. Upon receipt, corn syrup is placed into large storage tanks and is then sent through pipes to production. Loads of corn syrup pass continuously through these tanks. It is impossible to know when a particular shipment of corn syrup has been depleted or into which specific finished candy the corn syrup was used.

While FDA says that it does not intend to require dedicated storage facilities or reconfiguration of manufacturing plants, we nevertheless are concerned by the vagueness and subjectivity of the phrase "reasonably available."

c. The definition of "recipe" should be revised to include the quantitative or percentage formula used to manufacture a food.

Under the proposed rule, recipes for food are excluded from the record keeping requirements. A "recipe" is defined as "the quantitative formula used in the manufacturing of the food product, but not the identity of the individual ingredients of the food." CMA and NCA request that the final rule modify the proposed definition of "recipe" to include both the quantities and percentages of ingredients used in a food. The percentage of each ingredient used in a food is confidential information and is not needed by FDA to conduct a tracing investigation.

2. FDA should separately issue guidance setting forth procedures for protection of trade secret and confidential information obtained by FDA under section 306 of the Bioterrorism Act.

Section 306 of the Bioterrorism Act is self-effectuating, so FDA has authority to obtain access to records now without issuing any implementing regulations. It is important that any trade secret or confidential information obtained by FDA under this new authority receive appropriate protection from public disclosure. CMA and NCA urge FDA to promptly issue a guidance document outlining how the agency intends to exercise this new authority and explaining what procedures and standards will be followed to protect trade secret and confidential information.

3. The final rule should give companies more time to make records accessible to FDA.

The proposed rule would give companies only four hours to produce records in response to an FDA request made during normal business hours, eight hours if the request is made outside of normal business hours. Failure to produce records within the required timeframe would subject a company and its executives to criminal liability.

CMA and NCA believe the proposed time limits for production of records are unreasonable. Some companies, especially smaller businesses, need to move records to offsite storage every few weeks. While records stored offsite can be retrieved quickly in an emergency, the proposed time limits of four hours and eight hours are unworkable. CMA and NCA urge FDA to provide that records must be produced in a reasonable period of time. The courts have been able to determine what constitutes reasonable times and places for inspection under section 704 of the FD&C Act, so too can they determine what is a reasonable period of time to produce records under the Bioterrorism Act. If FDA nevertheless determines that a time limit must be written into the regulations, CMA and NCA believe that companies should be given 24 hours to produce records in response to an official written request from FDA. The final rule should clarify that the clock begins to run from receipt of a written request, not an oral request, for records from FDA.

4. The final rule should more carefully delineate the circumstances in which FDA may obtain access to the required records.

The proposed rule provides that required records must be made available to FDA when the agency has "a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals." 68 Fed. Reg. at 25,239. There appears to be no other limitation on the circumstances in which FDA may obtain records access.

It is clear from the Bioterrorism Act and its legislative history that Congress intended to impose additional constraints on FDA's exercise of its new records access authority. FDA's

reasonable belief that an article of food is adulterated and poses a threat of serious adverse health consequences is a necessary, but not a sufficient, condition for demanding records access. The agency must also have a specific need or purpose for obtaining access to records.[1] CMA and NCA believe that section 306 of the Bioterrorism Act and its legislative history authorize FDA records access only when required records are needed to: (1) determine whether an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, or (2) conduct a tracing investigation.[2] We request that the final rule confirm this and make clear the circumstances in which FDA may obtain access to required records. In addition, the final rule should require that an FDA written request for records be accompanied by a written statement delineating the specific records being requested and summarizing the evidence on which FDA is basing its reasonable belief that the article of food in question is adulterated and presents a threat of serious adverse health consequences or death to humans or animals.

* * * * *

We appreciate this opportunity to comment.

Respectfully submitted,

Lawrence T. Graham/rah

Lawrence T. Graham
President
National Confectioners Association

Lynn Bragg/rah

Lynn Bragg
President
Chocolate Manufacturers Association

---

[1] "The managers envision procedures whereby no agency personnel will have access to records without a specific need for such access...." *Congressional Record* H2858 (May 22, 2002) (managers' report).

[2] FDA may inspect 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." 21 U.S.C. § 350c(a). The legislative history makes clear that Congress also intended to give FDA records access when necessary for a tracing investigation.