

Procter & Gamble

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*The Procter & Gamble Company
General Offices
2 P&G Plaza, Cincinnati, Ohio 45202*

May 14, 2004

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

RE: Docket Number 02N-0276
Registration of Food Facilities Under the Public Health Security and Bioterrorism
Preparedness and Response Act

Dear Sir or Madam:

The Procter and Gamble Company welcomes the opportunity to submit comments pertaining to FDA's Notice of Proposed Rulemaking for Registration of Food Facilities published on April 14, 2004 (FR Vol. 69, No.72, pp. 19766-19767). The Procter & Gamble Company ("P&G") is an international consumer product company headquartered in Cincinnati, Ohio that markets consumer products in over 160 countries around the globe. In the United States, P&G products under FDA jurisdiction include those regulated as human and animal foods, dietary supplements, Rx and OTC drugs, cosmetics, and medical devices. P&G food products include Folgers coffee, Iams pet foods, and Pringles potato crisps.

On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 into law. P&G supports the goal of enhancing the security of the U.S. food supply. Section 305 of the Act requires registration of domestic facilities and certain foreign facilities engaged in manufacturing, processing, packing or holding food for consumption in the U.S. We believe reasoned final regulations and guidance from FDA are essential for implementing the Act in an orderly manner that enhances food safety and food security while minimizing uncertainty and disruption to the U.S. food supply and to the parallel systems in place for nonfood consumer product import, manufacturing and distribution. P&G submitted comments on this important topic during FDA's initial open comment period in August, 2002 prior to drafting of this proposed regulation, again, in May, 2003 after the proposed regulation was issued, and we appreciate this opportunity to comment once more.

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Our Specific Comments are as follows:

1. The current FDA Regulation and Guidance Requires more Clarity to Facilitate Implementation and Industry Compliance.

Section 305 of the Bioterrorism Act requires registration of facilities engaged in the manufacturing, processing, packing, or holding of food for consumption in the United States with exceptions for farms, retail food outlets, restaurants, non-profit food establishments, and certain fishing vessels. One of the major objectives of this FDA Registration regulation is to define these exceptions in a manner that is clear, implements the intent of the Act, ensures security of the food supply, and is not overly disruptive to commerce. FDA is to be commended on these efforts it has expended on this effort to date.

Since the Interim Final Rule was issued in October 10, 2003, a number of questions regarding facility registration status have been identified and forwarded to the Agency. To date, many of these questions have not been addressed satisfactorily by the Agency. Recent comments from FDA suggest this may be a result of an Agency presumption that these are low priority questions. Comments from FDA have suggested if the facility-type in question was not part of the Agency's economic analysis, the facility is likely exempt. This type of response provides insufficient clarity for industry and those striving to comply with this new regulation. While the Agency's response may be a result of a current Agency resource priority decision necessary in order to allocate resources to other Bioterrorism regulation work such as those being expended on development of the Recordkeeping regulation, these questions nevertheless have a significant bearing on implementation of the Bioterrorism Act in an orderly and predictable manner. Large companies interact extensively with smaller companies and those smaller facilities are looking to the large companies with assistance in interpreting the Interim Final Rule. Lack of clear answers from the Agency only prolongs the uncertainty.

Examples of questions that remain unanswered:

A. Doctor and Dentist Offices that Provide Food Samples to Patients

Doctors, dentists, and veterinarians commonly provide "food" product samples to patients. Distribution of dietary supplements, regulated as food under US regulations, has become a common practice in the US, especially as nutrition, diet, and obesity has become more prevalent within the US. Dentists distribute disclosing tablets to children to encourage better brushing habits. Together, samples help patients recognize the personal benefit of a specific type of product and/or can reinforce a specific patient behavior. Many physicians are indicating a preference to discontinue "food" sample distribution over registering under the Bioterrorism Act. We recommend that FDA add direct-to-consumer distribution of product samples to the definition of retail food outlets.

B. Non-Food Businesses providing Food Samples to Employees or the Public

Many facilities whose primary business function does not involve manufacturing, processing, packing, or holding food may host an event where they provide food samples to the public or to members. This may be an automobile dealership providing soft drinks and hot dogs to the public or a Fortune 500 company hosting an annual meeting for its employees or shareholders. In these

cases, providing food may be a promotion or a necessity. In these instances, it is unclear how registration enhances food security versus other existing systems. We recommend that FDA add direct to consumer distribution of product samples to the definition of retail food outlets or restaurants.

C. Non-Profit Organizations Conducting Consumer Research in For-Profit Facilities

Some non-profit organizations use facilities donated by other non-profit organizations or by industry. Locally, banks, nursing homes, healthcare facilities, and insurance companies provide meeting space for non-profit organizations. Many of these non-profit organizations raise operating funds by participating in consumer product tests, including food product tests. The Interim Final Rule appears to require the host non-food facility to register in order to allow non-profit testing with food products to continue. The Interim Final Registration rule exempts “non-profit food establishments”, defined to mean “a charitable entity that prepares or serves food directly to the consumer or otherwise provides food or meals for consumption” and meets 501(c)(3) of the IRS Code. We recommend that FDA clarify the definitions of “establishment” and “organization” in regard to non-profit organizations.

We encourage the Agency to recognize these are significant questions that they need logical, practical and timely answers.

2. The Obligations and Duties of a US Agent Remain Unclear.

The Interim Final Rule emphasizes that a US agent is “required to reside or maintain a place of business in the US and to be physically present in the US”. FDA also states that an agent needs to be “accessible to FDA 24 hours a day, 7 days a week” unless a facility provides alternate emergency contact information.

The Interim Final Rule doesn’t clearly define the duties and responsibilities of a US agent or the rights of a US agent. As a result, it can be difficult for facilities to evaluate and select a US agent or for individuals to agree to be a US agent. When an individual is designated to be a US agent, how will FDA interpret the requirement to be “accessible 24 hours a day, 7 days a week”? Are US agents prohibited from traveling by air? Are they required to hire an additional staff person to cover for them during illness, or travel? Is FDA requiring all agents to be companies?

Finally, the Interim Final Rule on Registration doesn’t make provision for a foreign facility to waive a US agent and submit information directly to FDA. Many facilities located outside the US are owned by or are subsidiaries of US companies and would simply prefer to interact directly with the FDA and not require an intermediary that serves no purpose other than meeting the Act. In these cases the role of US Agent adds cost and complexity for the facility and the parent company with no obvious benefit.

3. Duties and Obligations of a Registered Facility Remain Unclear.

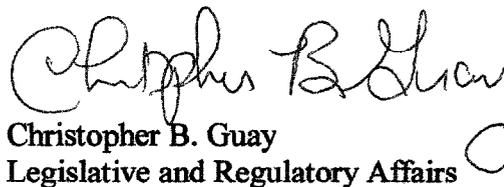
FDA has indicated that facilities subject to the registration requirements of Section 305 of the Act may be subject to inspection. The nature of these inspections have not been specified by the Agency and FDA inspectors during the past 6-9 months have suggested that inspections in the future could involve record review even during non-emergency situations. It would be extremely

valuable to all parties involved if FDA elucidated its needs and expectations for bioterrorism-related inspections before inspections like these begin in earnest. This would assist facilities interested in promoting biosecurity of the food supply and in complying with FDA regulations know what to expect and what their rights are in these new inspections, Specifically, will inspections be announced or unannounced? Will they be random or a result of a risk management process? What evidence is necessary to assure FDA that adequate records are being maintained by the facility? What is the scope of the inspections? The more information FDA can or is willing to share, the greater the likelihood of assuring a secure food supply. We encourage FDA to be as open with its industry partners as possible in order to reach our mutual goal of a safe and secure food supply.

The Procter & Gamble Company appreciates the opportunity to comment on this proposed amendment and I would be happy to discuss any of these comments in more detail. I can be contacted at (513) 983-0530 or guay.cb@pg.com.

Sincerely,

THE PROCTER & GAMBLE COMPANY
North American External Relations



Christopher B. Guay
Legislative and Regulatory Affairs