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

RE: Docket Number 02N-0277
Public Health Security and Bioterrorism Preparedness and Response Act of 2002
Section 306: Maintenance and Inspection of Records for Foods
Request for Public Input

Dear Sir or Madam:

Submitted herewith in duplicate are The Procter & Gamble Company's comments in response to FDA's July 17, 2002 request for public input prior to the development of new regulations required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Act"). 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. P&G markets products in the US regulated by FDA (food, cosmetics, over the counter ("OTC") drugs, medical devices, dietary supplements, animal foods, and Rx drugs) as well as products regulated by other Federal agencies (laundry detergents, paper towels, and cleaning products).

On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 into law. This law requires FDA to promulgate new regulations in several sections within 18 months or the law will take effect automatically. P&G strongly endorses FDA's objective to finalize the required regulations within this timeframe. Without final regulations, we believe implementation of the Act could be highly disruptive not only to the US food supply but to US nonfood consumer product manufacturing and distribution systems. We also appreciate the Agency's willingness to seek early input on regulation development and we submit the following comments in the spirit of this cooperative endeavor.

02N-0277

C/P

1. Allow Use of Existing Records and Systems to the Greatest Extent Possible.

The Act requires companies who manufacture, process, pack, transport, distribute, receive, hold, or import food to establish and maintain records identifying the immediate previous sources and immediate subsequent recipients of food. Per the Act, FDA may access these records in order to address credible threats of “serious adverse health consequences or death to humans and animals”.

We strongly suggest FDA implement performance-based recordkeeping regulations in a manner that allows for maximum use of existing records and systems while minimizing the need for creating new records for the sole purpose of the new regulations. This is consistent with Congressional intent to minimize the potential costs, inefficiencies and interruptions to the US food chain as a result of the Act. Moreover, the current documents created by companies’ compliance with current Good Manufacturing Practices (“cGMPs”) and other existing production standards are more than adequate to meet the FDA’s need to trace shipment of foods between facilities.

Individual companies should be given the flexibility to maintain records in a manner conducive to their business operations. Currently, several common business and shipping records such as Purchase Orders and Bills of Lading contain information pertaining to the parties involved in the transfer of product from one facility another. These have been traditionally been sufficient for business customers to track product distribution when needed. Establishing requirements consistent with current records permits companies to routinely maintain the records FDA requires using existing forms and existing systems, thus lessening disruption.

Under circumstances where FDA actually needs to inspect records such as a Purchase Order, companies should be permitted to provide copies of these records with sales data, product formulations (recipes), financial data, pricing data, personnel data, or research data redacted or to develop a record for FDA review comprised of the data contained on the original records. The Act specifies information of this type is excluded from the scope of the regulation and its presence on a record containing information subject to the regulation should not require its disclosure.

2. When and Where does Recordkeeping Start?

The Act requires records to be maintained to allow FDA to identify the immediate previous source and immediate subsequent recipient of food and food packaging to address credible threats. For a US company bringing product into the US, where does the record keeping requirement formally start; is it the first receipt of product in within the boundary of United States and its territories, when a US registered company with a facility in a foreign country receives the product before import into the US, when a US company takes title to the product, or when a company takes ownership FOB when a vessel leaves port?

We recommend that physical location of the product, not ownership or title, should be the primary factor in determining where and when record keeping under the Act commences. The first nonexempt facility within the US and its territories to receive and/or manufacture the food article should be the first facility required to maintain records of the source of the article and the subsequent recipient of the article. We believe this is consistent with the Act's intent to allow tracking of product movement, not necessarily product ownership. Similarly, for product purchased from a Futures Exchange, shipment of the food article to a nonexempt facility within the US is the first point where the recordkeeping should be required. Otherwise, the Act could be interpreted to require recordkeeping at foreign facilities where FDA's jurisdictional reach is limited. In addition, imposing these requirements on foreign facilities, or requiring US companies to impose these requirements on their foreign suppliers, would increase inefficiency and cost, while doing little to protect the US food supply.

When this Section of the Act takes effect in or before December 2003, how will food articles already in the US be regulated? We recommend FDA grandfather any food or food component already in the US when this provision takes effect, and that FDA begin enforcing the requirements of the Act on food articles manufactured or imported into the US on the day the Act and its corresponding regulations take effect. This is especially critical because some food ingredients such as coffee and grains may be imported, manufactured, and/or stored for 3-4 years before being incorporated into food for consumption. Some of these food articles already in distribution before the Act was signed into law in June, 2002 will still be in distribution after this regulation takes effect. If FDA enforces the registration, prior notice, recordkeeping and other requirements of the Act against previously existing materials, FDA would force actual compliance with the Act prior to the completion and understanding of the Act itself as well as the proposed and yet-to-be-drafted accompanying regulations. This could create immediate compliance issues, massive supply chain interruptions, product outages, increased costs for companies and consumers and inadequate lead times for companies seeking to comply with the Act and FDA regulations.

3. What Records Should be Maintained?

The Act requires a facility to maintain records identifying the immediate previous and subsequent facilities that possessed a given food article. It also gives FDA access to all records relating to the manufacturing, packaging, processing, distribution, holding receipt, and importation of an article of food held by that party (paper and electronic). The required recordkeeping and access to records provisions are separate and distinct. In order to avoid any implication that the "access" portion of the Act could be read as an affirmative obligation on companies to maintain all of the types of records mentioned above in order to provide FDA access to them, FDA should make clear in the regulations that the only records required by the Act are as follows:

Article Identity and, if available, Brand Name,
Name and Address of Site Food Article is being Shipped from,
Name and Address of Site Food Article is being Shipped to,
Name and Address of Carrier

This would be consistent with the Act's explicit language requiring recordkeeping sufficient to trace food articles to the party immediately preceding and subsequent to the company supplying the information.

In addition, FDA should define "records relating to manufacturing, packaging, processing, distribution, holding, receipt or importation of an article of food held by that party (paper and electronic) " to mean only those records kept in the ordinary course of business and required for compliance with cGMPs as described in FDA's previous regulations. This would provide FDA with all necessary information and be consistent with Congressional intent to protect the US food supply without forcing companies to create new records and documents solely for the purpose of meeting the new regulations.

Food facilities in the US are required to operate according to cGMPs. These requirements encompass facility operations, from raw material receipt to manufacturing, packaging, and finished product testing, and the creation and maintenance of certain documentation showing the internal flow of each operation. We believe that required records for a food manufacturing, processing or packaging facility should be consistent with those records required per cGMPs. Asking these facilities to maintain additional or separate records in addition to cGMPs will be duplicative and logistically complex.

Some manufacturing operations are not conducive to linking incoming records to records of outgoing finished product. This is especially true for food commodities that are consistently commingled and mixed prior to purchase and/or use by companies as food ingredients. The result is a loss of specificity in directly and conclusively linking an incoming lot of a raw material to an outgoing processed finished product. FDA needs to specifically address how it will resolve issues relating to commodity and ingredient commingling with respect to the recordkeeping requirements in the Act.

While batch processing under ideal circumstances allows a manufacturer to know which lot of each raw material went into each production lot, in these cases, it is impossible to directly or conclusively link use of Ingredient X, Lot 10 to Finished Product Z Lot 65. Site operations and engineering personnel may be very confident that Lot 10 will be a mostly in Production Lots 65, 66, 67 with traces in 68 and 69 and essentially none in lots thereafter, but that may be based on judgment and knowledge of the system rather than detailed validation studies. Adding to the complexity are situations involving systems where raw material lots are commingled. This practice is commonly used for commodity products stored in silos. The silos typically feed manufacturing operations directly and when one silo gets close to being empty and newly received lots are added to the silo.

The net result is that tracking finished product directly to its raw material lots and sources will not always be precise in existing food facilities. An FDA investigation is apt to lead to two or more raw material lots of certain commodity ingredients. While plant records in combination with manufacturing site knowledge should provide sufficient

information for an FDA investigation, FDA should provide guidance in their regulation regarding how they plan to handle these situations in a manner that will not impose undue burden on companies using these ingredients in food for distribution to consumers.

4. Ingredients Should be Regulated by Intent

Sections 301 through 315 of the Public Health Security and Bioterrorism Preparedness and Response Act should be applied only to food and ingredients intended for use in food. Ingredients intended for use in anything other than food (cosmetics, laundry detergent, OTC drugs, medical devices, etc.) should not be regulated under these Sections once the intent to use them for non-food uses has been established. This is clearly consistent with Congressional intent to protect the food supply.

This issue is of particular importance because ingredients commonly used in food products are also used as components and ingredients in non-food products. In fact, foods, cosmetics, OTC drugs, laundry detergents, and many consumer product formulations contain many of the same ingredients. For example, both a food and non-food product may contain a common colorant (an FD&C Dye), sweetener (saccharin), preservative (sodium benzoate), buffer (calcium phosphate), chelator (citric acid), emulsifier (PEG), flavor (mint), solubilizer (propylene glycol), thickener (carrageenan) and/or humectant (sorbitol). There are alternate ingredients for each functional class cited above that are used in foods and nonfoods alike in the US. The vast majority of nonfood consumer products marketed in the US contain ingredients also found in food products, including the most common of all, water. Because these individual components or ingredients are “food” in some instances and “non-food”, in others, FDA should create a system or mechanism to determine the importer/manufacturer/distributor’s intended use of the each item in the context of the Act before regulating an item under the Act. Without distinguishing the status of common ingredients based on intended use, companies that import and/or use versatile ingredients automatically would be forced to follow the registration, notice, recordkeeping and other requirements. Importantly, many non-food businesses using versatile ingredients believe they are exempt from these provisions of the Act and are not represented in these proceedings to date. Moreover, it would likely strain FDA resources to try to enforce the Act in this manner. We recommend a simple statement by the importer/manufacturer/distributor should suffice to determine which ingredients are “foods” subject to the Act. For example, if a company purchases food grade citric acid for shipment to a detergent facility for use entirely for laundry detergent, recordkeeping and registration per the Act should not be required.

A primary factor distinguishing factor between drugs, devices, cosmetics and foods is product intent as indicated in the following definitions in the Federal Food, Drug and Cosmetic Act:

§201(f), defines “food” to be “Articles used for food or drink for man or other animals, 2) chewing gum, and 3) articles used for components of any such article.”

§201(g) defines “drug” to be “Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and articles (other than food) intended to affect the structure or any function of the body of man or other animals and articles intended for use as a component of any articles specified [above]”.

§201(h) defines “device” to be “an instrument, apparatus, implement, machine, contrivance, implant, in vitro agent, or other similar or related article, including any component, part, or accessory.....intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals”

§201(i) defines “cosmetic” to be “Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance and articles intended for use as a component of any such articles.”

Importantly, these definitions also cover the components of these products. The ingredients of a drug product are regulated as drugs. The ingredients of a cosmetic are regulated as a cosmetic. The components of a food are regulated as a food.

Since the product lines of many US companies, including P&G, encompass both food products and nonfood products that use common ingredients, the new legislation appears to require us to distinguish when a common ingredient is and is not a food. We believe the best approach to determine what items should and should not be regulated under the Act is to require the responsible parties to declare their intended use of articles to FDA upon distributing or importing. For example, a common food ingredient such as sodium saccharin would be regulated as a food if the facility declared it would be used in foods. If saccharin were declared for use only in cosmetics, however, it would not be subject to the Act.

5. Record Keeping for Products with a Short Shelf Life

The Act requires sender and recipient records to be maintained for no more than 2 years. While this is generally not an issue for most shelf stable food products and food ingredients, for perishable products and products having expiration dates of just a few weeks or a few months, maintaining records out to 2 years seems to provide no real meaningful value in protecting the integrity of the food supply. Any acute harmful effect suggestive of illicit activity or compromised food quality would have appeared within the product’s expiration date or shortly thereafter---long before 2 year time limit suggested by the Act. This would involve added expense, inefficiency and complexity without providing FDA or the consuming public any incremental safety benefit.

We recommend record keeping requirements be established to be 3 to 6 months beyond a product’s expiration date or 24 months, whichever is shorter. The concept of maintaining records for a specified period of time beyond a product’s expiry date is utilized by other FDA regulated products such as OTC drugs and cosmetics and appears to be a common and reasonable approach for handling multiple differing food articles with expiration dates ranging from days, to weeks, to months to years.

6. Exemptions for Research and Development Activity

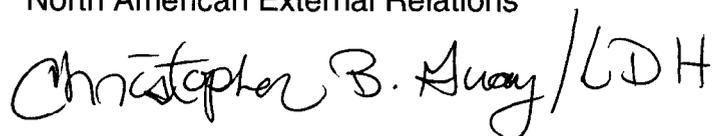
Since R&D involves activity with products that are not commercially available, involves small-scale studies conducted under supervision, and involves product made under cGMPs, and involves proprietary formulations, we believe exempting R&D activities appears consistent with the intent of the Act. These materials are easily traceable, are consumed by a minimal number of consumers and do not pose a widespread threat to the public. Further, any issues arising from R&D studies could be quickly traced and resolved.

As FDA develops regulations for record keeping, we encourage the Agency to take maximum advantage of the systems already in place and limit the need for additional records. Sensitive information outside the purview of the Act must be protected from disclosure. Clarity regarding where, when, and how record keeping commences once FDA regulations take effect is crucial due to the dynamic nature of the distribution network. FDA should further allow shortened record maintenance for products with short expiration dates. Finally, industry needs FDA to clearly affirm that ingredients become nonfoods (cosmetics, devices, OTC drugs, etc.) once their intent is established, presumably by shipment for use in facilities that do not manufacture foods or ship raw materials to food producing facilities.

The Procter & Gamble Company appreciates the opportunity to comment on this new rule 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

A handwritten signature in black ink that reads "Christopher B. Guay" followed by the initials "CDH" in a larger, stylized font.

Christopher B. Guay
Legislative and Regulatory Affairs