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*The Procter & Gamble Company
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November 18, 2005

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

RE: Docket Number 2005N-0349
Food and Drug Administration Survey of Current Manufacturing Practices in the Food Industry

Dear Sir or Madam:

The Procter and Gamble Company welcomes the opportunity to submit comments pertaining to FDA's Proposed Survey of Current Manufacturing Practices in the Food Industry published on September 14, 2005 (FR Vol. 70, No.177 pp. 54390-54391). 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.

P&G commends FDA for its continuing and sustained efforts to help ensure the safety and security of the US food supply. We believe updating Food Good Manufacturing Practices (Food GMPs) has the potential to improve the integrity of the US food supply, benefiting both the US consumer and strengthening the US food industry. Further, we support FDA's approach to request food industry practice data early in the rule-making process, before issuing proposed regulations, as a means to help ensure clear, reasonable, and actionable final rules that do not require rework and substantial clarification.

As FDA sets out to develop updated GMPs for food, we encourage the Agency to consider a developing a tiered approach based on actual and potential risk. A tiered approach would focus more attention on those products, processes, and controls that significantly can impact product quality, safety, and integrity. This would result in increased investment in and more stricter

2005N-0349

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control of higher risk operations when compared to the average. Additionally, this approach would not require the same significant investment in operations where there is little or no perceived public health or operational benefit.

Where ever possible, we also encourage the Agency to deploy a Food GMP regulation that is objective-based and principle-based, rather than one that mandates a specific procedure or protocol that must be employed. We believe an objective-based regulation creates incentives that encourage innovation, which can lead to greater future public health benefits. Capriciously mandating a specific procedure may impact a much broader target of operations than originally envisioned by the Agency, prompt changes merely for the sake of making changes, and limit the incentive for finding superior and/or more efficient ways to achieve a desired endpoint.

Training Procedures and Practices for Food Production Personnel

We encourage the Agency to gather sufficient data to understand the broad and specific impacts of a proposed regulation on large multinational companies, small US companies, different kinds of food products (for example, baked products, canned products, refrigerated products, frozen products, fresh products) and different kinds of operations (packing, cooking, storing, processing, etc.). We believe increased FDA understanding of the industry will lead to better reasoned proposed and final regulations. The recent Prior Notice and Recordkeeping regulations promulgated by the Agency demonstrate the consequences of the Agency not taking [not being given] the time understand the industry before proposing a regulation—a proposed regulation with too many flaws takes a lot of FDA and industry time to fix, creating so many issues that it may not be “100% fixed” even when issued as a final regulation—requiring more effort to clarify what the regulation means.

From a training perspective, we encourage the Agency to focus its information collection efforts on the documentation of knowledge and skill development, training plans for critical roles, qualification processes, training course development and ownership, and systems capable of demonstrating training and qualification. Importantly, we encourage the Agency to be as specific as possible in asking questions and recording answers since many common or general terms can mean vastly different things to different people and different organizations. Asking “What per cent of plant personnel are adequately trained?” is less likely to result in meaningful data to assist in writing Food GMPs while a question such as “List the training requirements to become a production line supervisor?” may provide better perspective on the types of training being conducted across the industry. We believe asking specific questions that require specific responses will take interested parties at least 2-4 times longer to complete than the time estimated by FDA in the Federal Register notice. This is based on the assumption that the number of questions being asked could increase by about 25% and the time to complete responses will also increase.

Sanitation and Pest Control

We recommend that questions on this topic focus on a facility’s systems which function to ensure the site is clean and orderly, do not attract or harbor pests, prevent cross contamination between products, and ensure appropriate product quality. This would include housekeeping

systems covering planned activities and unplanned events, equipment sanitization and cleaning procedures and systems, and systems monitoring for pest activity. Many pest control activities may be contracted so procedures for delineating duties and managing the effectiveness of the contractor may also be evaluated.

Allergen Control Practices and Procedures

We recommend that questions related to allergen control practices focus on the steps utilized to prevent cross contamination between raw materials/products containing an allergen and other raw materials/products and also the procedures used to monitor and evaluate the effectiveness of these steps. Importantly, the controls and procedures necessary to limit cross contamination can vary dramatically as a result of the particular allergen involved, its form or size, the physical layout of the facility, etc.

Control of Food Receipts and Processing

Questions should focus on procedures that demonstrate and document that the materials and components used to make, package, and ship a product for customer or consumer are known and of acceptable quality. This would include assuring receipts are properly evaluated and qualified under controlled conditions, processed products meet specifications and production standards, materials are controlled while in storage, and that rework, recycling or reblending is properly controlled and documented.

Recordkeeping Practices

Many companies do not have the same food recordkeeping systems in place throughout the company. Many historical factors can contribute to this, among them differing facility locations, the age of the plant and plant equipment, product differences, and product acquisitions. Harmonizing systems within a company is a time consuming and expensive process, so it generally occurs where or when there is a need for it such as resulting in changes being made and therefore systems plants having different ages, acquisitions, or product complexity. Therefore, we support FDA's initiative to collect data by facility but also recommend facilities to combine input where common systems and approaches are utilized.

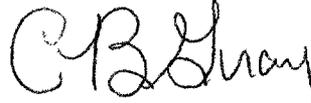
Primary Plant Operations

Questions should adequately define the products processed at the facility, the kind of manufacturing operations conducted within the facility and the nature of the control mechanisms utilized within that facility.

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

A handwritten signature in black ink, appearing to read "C. B. Guay". The signature is written in a cursive, flowing style.

Christopher B. Guay
Regulatory and Technical Affairs