

22 March 2006

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

Comments Re: Docket Number 2004-0230 - Food CGMP Modernization

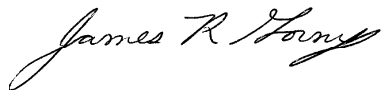
Dear Sir or Madam,

The United Fresh Fruit & Vegetable Association (United) is a national trade association representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States. United helps build strong partnerships among all segments of the industry, promotes increased produce consumption; and provides scientific and technical expertise essential to competing effectively in today's marketplace.

United provides technical information, representation and knowledge to our member companies, so that they may grow, pack and market convenient, nutritious and wholesome fresh produce. Assuring consumer safety is an issue that United and the fresh produce industry take very seriously as it is of paramount importance. United and our member companies are steadfastly committed to providing fresh, safe and wholesome products to consumers.

United respectfully submits the following comments regarding the U.S. Food and Drug Administration's "Food CGMP Modernization — A Focus On Food Safety" [Docket No. 2004-0230].

Respectfully,

A handwritten signature in cursive script that reads "James R. Gorny".

James R. Gorny, Ph.D.  
Vice President, Quality Assurance and Technology

***Comments to the FDA Regarding CGMP Modernization [Docket No. 2004–0230]  
February 1, 2006***

***James R. Gorny, Ph.D.  
Vice President, Quality Assurance and Technology  
United Fresh Fruit & Vegetable Association***

Founded in 1904, the United Fresh Fruit and Vegetable Association (United) is a national trade association representing member growers, shippers, packers, processors, marketers and distributors of fresh produce in the United States. United members provide the leadership to shape business, trade and public policies that drive our industry. Working with thousands of industry members, United provides a fair and balanced forum to promote business solutions; helps build strong partnerships among all segments of the industry; promotes increased produce consumption; and provides scientific and technical expertise essential to competing effectively in today's marketplace. We have a direct and vested interest in food safety, and as such, the Agency's efforts to revise the current good manufacturing practice (CGMP) regulations. United applauds the Agency for considering such a revision given the fact that the rule was last updated in 1986.

**Issue:**

The CGMP Modernization working group has recommended that the agency consider removing the exclusion from CGMP compliance in 21 CFR Part 110.19 for establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities.

**Recommendations:**

**1) FDA Regulatory Authority Is Currently Sufficient To Assure Produce Food Safety**

The 21CFR Part 110.19 CGMP RAC exclusion should not be amended because the Agency already has at its disposal stringent regulatory authority regarding the harvest, storage or distribution of fresh fruits and vegetables. The Agency already has statutory authority to institute court proceedings to restrain violations of the Act (FD&C Act § 302, 21 U.S.C. § 332), criminally prosecute responsible persons for violations of the Act (FD&C Act § 303, 21 U.S.C. § 333), and seize adulterated or misbranded product (FD&C Act § 304, 21 U.S.C. § 334).

**2) Raw Agricultural Commodities Are Not Manufactured Foods**

The current Good Manufacturing Practices (CGMPs) as set forth in 21CFR110 provide guidelines that assure that food for human consumption is safe and has been prepared, packed and held under sanitary conditions. The CGMPs provide food processors, such as fresh-cut produce processors, with the core principles of sanitary food handling and they serve as well recognized and agreed upon standards of conduct and operation. Revising the CGMPs in a manner outside of their current scope of manufactured food products to include raw agricultural commodities (RACs) is inappropriate because these food products are fundamentally different from manufactured food products in that they cannot be practically grown, harvested, stored and distributed in manner that is currently prescribed by the CGMPs for controlled food manufacturing environs. CGMPs are well defined and function well within the control environs

of a food processing plant however, CGMPs are not universally appropriate or applicable in production, harvest, storage and/or distribution of RACs. As food handling operations move from a confined four walled food processing facility to a three walled packinghouse operation and/or back to an open agricultural growing operation, it is obvious that not all CGMPs requisites could even possibly be implemented. Application of CGMPs to all RAC harvest operations would not be practical to implement and would potentially have unintended consequences such as the reduced availability of some from fruits and vegetables.

Good Agricultural Practices (GAPs) have been widely accepted and implemented by the fresh fruit and vegetable industry and as formulated provide the produce industry with an excellent description of broad prescriptive actions that may be taken to enhance produce food safety. Numerous retail and wholesale buyers have made compliance to GAPs, and subsequent independent third-party audits to assure compliance with GAPs, a requirement for the purchase of fresh fruits and vegetables. GAP audit criteria for storage and distribution operations are commonly derived from CGMP provisions for these operations. It should also be noted that CGMPs are already adhered to by wholesale, retail and food service storage and distribution operations.

The Agency would best serve public health and safety by focusing Agency efforts on continued refinement and promotion of GAPs guidance which is the appropriate means of assuring the safety of RACs.

### **3) Limited Applicability of CGMPs to Fresh Produce**

The CGMPs provide food processors or manufacturers, such as fresh-cut produce processors, with the core principles of sanitary food handling and they serve as well recognized and agreed upon standards of conduct and operation. The current CGMPs are well written for food manufacturing operations, in that they provide general guidance regarding regulatory expectations of performance and conduct without being overly specific or prescriptive, and this aspect of the CGMPs accommodates the many diverse specific situations that are encountered in the food manufacturing industry today.

The entire food industry, including the produce industry, has undergone widespread change since the CGMPs were last revised and the nation's food safety regulations should reflect those changes. Specifically, the produce industry has seen a significant development and growth in the ready-to-eat foods category, for example bagged fresh-cut salads and baby whole peeled carrots. Fresh-cut produce processors already are obliged and do conform to CGMPs. As the valued-added produce industry segment has grown there has been increased adoption of operational practices whereby RACs may be trimmed and/or cored during harvest operations to enhance operational productivity. For these type of harvest operations, the produce industry has very prudently developed guidelines which draw heavily on the principles outlined in the CGMPs, to assure that these unit operations are done in a sanitary manner so as to reduce, control and/or eliminate food safety risk. This is one area of produce harvest operations where some CGMPs may be applicable because food contact surfaces used to trim or core produce have direct contact with portions of RACs that will be consumed.

However, CGMPs are not necessarily universally applicable to all RAC harvest operations. CGMPs requirements should not be applied for example to harvest implements such as knives and clippers used to harvest whole RACs (i.e. not trimmed and/or cored) because these tools only contact non-edible portions of fruits and vegetables such as the stem or core that is not

consumed. Application of CGMPs to all fresh produce RAC harvest operations would be terribly impractical to implement and add unwarranted costs with little to no actual food safety benefit.

Any revisions made to the CGMPs must be science-based; easy to implement and manage; and cost effective. The Agency must ensure that this foundational basis is not lost during the revision process. United recommends that the Agency revise and update current GAPs recommendations to incorporate appropriate specific limited portions of CGMPs into the GAPs guidance, in lieu of imposing a one size fits all CGMP approach to enhancing the safety of RACs during harvest, storage and distribution.

United would like to thank the FDA for the opportunity to offer comments. We look forward to working with the agency to develop realistic and effective approaches to enhance produce food safety. Please contact United Fresh Fruit & Vegetable Association at anytime you have questions, or for additional information.

Respectfully,

James R. Gorny, Ph.D  
Vice President, Quality Assurance and Technology  
United Fresh Fruit and Vegetable Association