development or approval, of a drug product, and conduct otherwise relating to the regulation of a drug product under the act.

As a result of the foregoing finding, Dr. Maria Anne Kirkman Campbell is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective as stated in the **DATES** section of this document (see section 306(c)(1)(B) and (c)(2)(A)(ii) and 201(dd) of the act (21 U.S.C. 321(dd))). Any person with an approved or pending drug product application who knowingly uses the services of Dr. Campbell in any capacity, during her period of debarment, will be subject to civil money penalties (section 307(a)(6) of the act (21 U.S.C. 335b(a)(6))). If Dr. Campbell, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, she will be subject to civil money penalties (section 307(a)(7) of the act). In addition, FDA will not accept or review any abbreviated new drug application submitted by or with the assistance of Dr. Campbell during her period of debarment (section 306(c)(1)(B) of the act).

Any application by Dr. Campbell for special termination of debarment under section 306(d)(4) of the act should be identified with Docket No. FDA–2006–N–0166 and sent to the Division of Dockets Management (see **ADDRESSES**). All such submissions are to be filed in four copies. The public availability of information in these submissions is governed by 21 CFR 10.20(j). Publicly available submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 22, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20295 Filed 8–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0455]

Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables; Request for Comments and for Scientific Data and Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments and for scientific data and information.

SUMMARY: The Food and Drug Administration (FDA) is requesting comments and scientific data and information that may assist the agency to improve the guidance to industry set forth in the ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,'' issued in 1998. Specifically, FDA is seeking information about current agricultural practices and conditions used to grow, harvest, pack, cool, and transport fresh produce; risk factors for contamination of fresh produce associated with these practices; and possible measures that FDA could implement that would enhance the safety of fresh produce.

DATES: Submit written comments and scientific data and information or electronic comments by December 31, 2008.

ADDRESSES: Submit written comments and scientific data and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments and scientific data and information to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to this document.

FOR FURTHER INFORMATION CONTACT: Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–2024.

SUPPLEMENTARY INFORMATION:

I. Background

A. Food Safety and Fresh Produce

FDA is responsible for ensuring the safety of all domestic and imported fresh fruits and vegetables consumed in the United States. Fresh fruits and vegetables are those that are likely to be sold to consumers in an unprocessed or minimally processed (i.e., raw) form. Fresh fruits and vegetables may be intact and whole, such as whole apples, or cut in the act of harvest, such as heads of lettuce and bunches of broccoli.

Because most fresh produce is grown in a natural environment, it is vulnerable to contamination with pathogens (i.e., bacteria or other organisms that can cause disease). Factors that may affect the occurrence of such contamination include agricultural and/or post-harvest water quality, the use of manure as fertilizer, the presence of wild or domestic animals in or near fields or packing areas, worker health and hygiene, environmental conditions, production activities, and equipment and facility sanitation. Consequently, the manner in which fresh produce is grown, harvested, packed, cooled, and transported is crucial to minimizing the risk of microbial contamination. (We use the term ''microbial contamination'' to refer to contamination with any microorganism.)

Data reported to the U.S. Centers for Disease Control and Prevention (CDC) indicate that between 1973 and 1997 reported outbreaks of foodborne illness in the United States associated with fresh produce increased in absolute numbers and as a proportion of all reported foodborne outbreaks (Ref. 1). (By ''outbreak,'' we mean the occurrence of two or more cases of a similar illness resulting from the ingestion of a common food.) Unpublished data compiled by FDA indicate that from 1996 to 2007 there were approximately 72 reported outbreaks of foodborne illness associated with approximately 20 fresh produce commodities. Of this total, 13 outbreaks were associated with tomatoes, 11 outbreaks were associated with melons, and 24 outbreaks were associated with leafy greens such as lettuce and spinach (Ref. 2). These outbreaks involved a number of pathogens, including *Escherichia coli* (*E. coli*) O157:H7 and *Salmonella* species, and involved both domestic and imported produce. These totals include only those outbreaks in which our investigation has indicated that the contamination of the produce was not a result of exposure to an infected food handler or other unsafe food handling practice at the place of preparation and consumption (i.e., home or restaurant). There have also been a number of reported outbreaks associated with fresh produce in 2008.

B. FDA's GAPs/GMPs Guide

FDA places a high priority on identifying and promoting measures that can reduce the incidence of foodborne illness associated with fresh produce. In 1998, FDA and the U.S. Department of Agriculture issued

guidance to industry entitled ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables'' (Ref. 3), to enhance the safety of fresh produce, to assist the fresh produce industry in addressing common risk factors in their operations, and to minimize potential food safety hazards. (The document is referred to hereinafter as the ''GAPs/GMPs Guide''—GAPs is an abbreviation of ''good agricultural practices'' and GMPs is an abbreviation of ''good manufacturing practices.'') While FDA recognizes current technologies cannot eliminate all potential food safety hazards associated with fresh produce that will be eaten raw, the GAPs/GMPs Guide emphasizes that implementation of risk reduction measures is critical to minimizing these potential food safety hazards. The agency has worked with the fresh produce industry and other food safety partners since the issuance of the GAPs/ GMPs Guide to promote its recommendations and to advance the scientific knowledge applicable to enhancing the safety of fresh produce, and the GAPs/GMPs Guide has been used as a basis for a number of food safety programs, both in the United States and internationally. Choices by buyers to purchase from producers and other suppliers that provide self- or third-party audit verification that they are following the GAPs/GMPs Guide have further promoted adoption of the guidance.

Subsequent to the issuance of the GAPs/GMPs Guide, FDA has undertaken a number of produce safety initiatives that have enhanced its understanding of the effectiveness of the GAPs/GMPs Guide in reducing the risk of produce-associated foodborne illness. Examples include the 2004 ''Produce Safety From Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption,'' commonly called the ''Produce Safety Action Plan'' (Ref. 4), which focuses on prevention of contamination, minimization of public health impacts when contamination does occur, communication with the public and stakeholders, and facilitation and support of research; the multi-year ''Leafy Greens Safety Initiative'' (Ref. 5), launched in 2006 in collaboration with the State of California, which involves assessment of practices and conditions at select farms and facilities in California, including adoption and implementation of good agricultural practice and good manufacturing practice recommendations (for packing houses) and requirements (for fresh-cut processing facilities); and the 2007 ''Tomato Safety Initiative'' (Ref. 6), a multi-year collaboration similar to the ''Leafy Greens Safety Initiative'' with the States of Virginia and Florida, as well as several universities and members of the produce industry.

Available data and FDA's experience suggest that the GAPs/GMPs Guide (and other public and private sector efforts) have accurately identified certain potential sources of microbial contamination of fresh produce, such as agricultural water and worker health and hygiene. Data and experience also indicate that the recommendations in the GAPs/GMPs Guide can be effective when implemented. However, the fact that outbreaks of foodborne illness associated with fresh produce continue to occur supports a close examination of the extent to which the recommendations in the GAPs/GMPs Guide have been implemented; the extent to which they have been effective, if implemented properly; and what additional or different interventions might be appropriate to reduce the risk of future outbreaks. The agency recognized when it issued the GAPs/GMPs Guide in 1998 that it would need to be updated ''[a]s new information and technological advances expand the understanding of those factors associated with identifying and reducing microbial food safety hazards'' (Ref. 3). In the 10 years since the GAPs/ GMPs Guide was released many changes have occurred in the produce industry, and a great deal of new knowledge and information have become available. In addition, the agency now has 10 years experience in implementing this guidance and observing how and the extent to which it has been implemented by the industry.

In addition to the initiatives described previously, in 2007 FDA held two public hearings to inform stakeholders about produce-associated outbreaks and to solicit comments to inform the agency in determining the next steps (Ref. 7). In both instances, the agency asked a series of questions. Among these questions, we asked whether FDA's current GAPs/GMPs Guide needs to be expanded or otherwise revised, and if the response was yes, we solicited comments about what areas need to be expanded or otherwise revised. Comments were generally in agreement that the basic principles set out in the 1998 guidance remain sound. However, they were split on whether FDA should update the GAPs/GMPs Guide and, if so, how it might be revised. Several comments suggested the GAPs/GMPs Guide should provide more specific and directive recommendations. A number of comments suggested that the GAPs/ GMPs Guide needs more explicit information to facilitate risk assessment. Other comments urged FDA to keep the GAPs/GMPs Guide broad in scope, and to focus instead on education/outreach to promote adoption of existing recommendations.

FDA has taken the comments received in response to the 2007 public hearings into consideration and incorporated relevant suggestions as it conducts the produce safety activities mentioned in this **Federal Register** document and other activities implementing the ''Produce Safety Action Plan.'' However, because most comments did not provide substantive information or data in response to this question, FDA has determined that it would benefit from another, more focused opportunity for public comment.

Thus, FDA is now soliciting comments and scientific data and information on any possible measures and technological advances that would assist the agency in improving the agency's current GAPs/GMPs Guide. Specifically, FDA is seeking information and comment on the issues and questions in section II of this document. When possible, please provide scientific information and data in support of your comments. In addition, please provide information as specific as is feasible about the estimated costs and benefits associated with your responses (e.g., the costs and benefits of current practices and/or the cost and benefits of any recommendations you may make). FDA is not seeking information and comment on issues of traceability in this document, because FDA plans to do so in the context of a public meeting.

II. Issues and Questions

Issue 1: The GAPs/GMPs Guide addresses potential sources of microbial contamination associated with a range of issues, or variables, such as: Water (both agricultural water and post harvest water uses); manure and municipal bio-solids; worker health and hygiene; packing facility sanitation; transportation; and traceback (Ref. 3). Data from our experience over the past decade support the inclusion of many of these issues as risk factors for produce-associated foodborne illness outbreaks. Some of these potential sources of contamination in particular, such as worker health and hygiene, water quality (pre- and post-harvest), domestic and wild animal issues, and facility and equipment sanitation have been cited frequently by investigators during inspections at farms and facilities that were implicated in outbreak investigations. On the other hand,

although there remains a significant potential for contamination, some issue areas, such as the intentional use of manure or bio-solids as an agricultural input, have not been cited as a potential source of contamination to the same extent. The current guidance does not attempt to rank the potential hazard variables in terms of relative risk or importance.

Question 1. Should any future GAPs/GMPs Guide rank or prioritize among potential issues according to relative risk or importance? If yes, please offer suggestions of how that information could most effectively be presented in a way that does not detract from the broad scope of the current guidance.

Issue 2: The GAPs/GMPs Guide tends to be arranged by issue area, while more recent industry commodity specific supply chain guidelines are divided according to where the commodity is within the supply chain (e.g., production, packing, distribution) and/or the chronological order of activities at each step.

Question 2. How should the GAPs/GMPs Guide be organized to enhance its usefulness?

Question 3. While the GAPs/GMPs Guide has been generally accepted and widely adopted, we know that there are entities in the fresh produce industry that are not aware of it. What measures can be taken, and by whom, to expand awareness by the fresh produce industry of the GAPs/GMPs Guide?

Question 4. How should the GAPs/GMPs Guide be modified to motivate all operations to implement? Please include information on economic impact.

Question 5. Can the GAPs/GMPs Guide be applied equally to, and implemented by, domestic and foreign growers and packers? If not, should the GAPs/GMPs Guide be revised to incorporate additional options or special considerations (e.g., utilizing draft animals for agricultural tasks) for application and implementation? Please explain.

Question 6. Is there a need for additional guidance to assist an operator in determining which provisions of the Current Good Manufacturing Practice regulations in part 110 (21 CFR part 110) (e.g., post-harvest water quality, disease control, cleanliness, and supervision) could be implemented voluntarily for operations that currently are excluded under § 110.19? If so, which ones?

Issue 3: Written food safety plans, sanitation standard operating procedures (SSOPs), standard operating procedures (SOPs), and monitoring records serve as useful tools for both industry and regulators. Such records assist operators to conduct operations in a manner that enhances the safety of fresh produce. For growers, an assessment of factors such as the field environment and agricultural inputs contributes to the development of written food safety plans and SOPs, and also helps to determine which factors should be monitored and the frequency of such monitoring. (The use of the term ''assessment'' refers to an evaluation conducted by, or on behalf of, a grower or operator to identify measures to enhance food safety.)

Written food safety plans, SOPs, SSOPs, and monitoring records also assist regulators to verify consistent and long-term implementation of certain practices. On-site inspections, either alone or in conjunction with records review, are another approach to such verification. (The use of the term ''inspection'' refers to an evaluation conducted by, or on behalf of, a regulator to evaluate whether operations comply with applicable guidance or regulations. The term ''audit'' refers to a self or third-party evaluation of whether operations are consistent with voluntary guidelines and written food safety plans or SSOPs developed by the grower, operator, or buyer.)

Question 7. Should the GAPs/GMPs Guide recommend that growers and/or other relevant operations develop a written food safety plan, written SOPs, and/or written SSOPs? If so, please describe the types of information or recommendations that you believe would be helpful.

Question 8. Records can be divided into the following two broad groups: (1) Records to facilitate traceback, and (2) non-traceback or operational records. Does the GAPs/GMPs Guide provide sufficient recommendations regarding record keeping? If not, please describe what would be most helpful and why, e.g., information about the record keeping regulation (21 CFR 1 subpart J), guidance on what makes a ''good'' record, guidance on periodic record review and verification, and required or recommended record retention times. What types of monitoring records or other documentation would be most useful to industry and regulators?

Question 9. The recent produce safety initiatives concerning leafy greens and tomatoes (Refs. 5 and 6) have highlighted the importance of performing environmental assessments (e.g., assessing water source quality, water distribution systems, animal presence, and other risk factors that may be associated with the production environment) before planting, throughout production, and prior to harvest. Would it be useful to enhance coverage of these concepts in the GAPs/GMPs Guide? If yes, please describe.

Question 10. Several newer produce safety programs, such as the California Leafy Green Products Handler Marketing Agreement (Ref. 8), incorporate recommendations (or requirements) for microbial testing. Does the information on microbial testing in the GAPs/GMPs Guide provide sufficient information to assist operators in designing a meaningful and cost effective testing program? If not, please describe what types of additional information would be most useful, such as how and where microbial testing might best be used to achieve food safety objectives, e.g., building a history of agricultural water quality, making best management decisions, verifying food safety operations.

Question 11. Some comments submitted in connection with the 2007 public hearings expressed concerns that field management activities intended to minimize microbial hazards, such as removing vegetation to reduce animal harborage near the production field, could have a negative, albeit unintended, impact on the environment and water sheds, among other areas. What data support these concerns? Could/should the GAPs/GMPs Guide do more to identify, address, and possibly mitigate unintended environmental consequences of food safety measures?

Question 12. Are there existing regulatory requirements at the Federal, State, or local level that act as a disincentive (or as an incentive) for growers or other operators to implement agricultural or manufacturing practices that should be taken into consideration when updating this guidance to reduce the risk of microbial contamination of fresh produce? If yes, please identify and explain.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket

management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site addresses, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. Sivapalasingam, S., et al. ''Fresh Produce: A Growing Cause of Outbreaks of Foodborne Illness in the United States, 1973 through 1997,'' *Journal of Food Protection* 67(10): 2342–53, 2004.

2. U.S. Food and Drug Administration, 1996 to 2007 Produce Outbreaks (unpublished compilation).

3. U.S. Food and Drug Administration, ''Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables,'' October 26, 1998, available at *http://www.cfsan.fda.gov/~dms/prodguid.html*.

4. U.S. Food and Drug Administration, ''Produce Safety From Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption,'' October 2004, available at *http://www.cfsan.fda.gov/~dms/prodpla2.html*.

5. U.S. Food and Drug Administration, ''Leafy Greens Safety Initiative—2nd year,'' October 4, 2007, available at *http://www.cfsan.fda.gov/~dms/lettsaf2.html*.

6. U.S. Food and Drug Administration, ''Tomato Safety Initiative,'' June 12, 2007, available at *http://www.cfsan.fda.gov/~dms/tomsafe.html*.

7. ''Safety of Fresh Produce; Public Hearings; Request for Comments'' (72 FR 8750, February 27, 2007), Public hearings held on March 20, 2007, and April 13, 2007, *http://www.regulations.gov/fdmspublic/component/main?main=DocketDetail&d=FDA–2007–N–0380*.

8. California Leafy Green Products Handler Marketing Agreement, available at *http://www.caleafygreens.ca.gov*.

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.cfsan.fda.gov/~dms/prodguid.html*.

Dated: August 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20187 Filed 8–29–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0466]

Over the Counter Cough and Cold Medication for Pediatric Use; Notice of Public Hearing; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public hearing; request for comments; correction.

SUMMARY: The Food and Drug Administration is correcting a notice that published in the **Federal Register** on August 25, 2008 (73 FR 50033). The notice announced a public hearing to obtain input regarding over-the-counter (OTC) cough and cold drugs marketed for pediatric use. Due to some confusion regarding electronic registration, this notice revises the electronic registration procedures, and corrects the address for the contact person.

DATES: The correction is effective September 2, 2008.

FOR FURTHER INFORMATION CONTACT: Faith Dugan, Food and Drug Administration, 10903 New Hampshire Ave., rm. 6182, Silver Spring, MD 20993, 301–796–3446, Faith.Dugan@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In FR Doc. E8–19657, published on August 25, 2008 (73 FR 50033), the following correction is made to **ADDRESSES**:

1. On page 50033, in the first and second columns, the **ADDRESSES** section is corrected to read as follows:

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

E-mail electronic registration to: Faith.Dugan@fda.hhs.gov. Anyone who has already registered via *http://www.regulations.gov* does not have to re-register. The agency will accept those registrations.

Submit electronic comments to *http://www.regulations.gov*. All comments should be identified with the docket number found in brackets in the heading of this document.

Transcripts of the hearing will be available for review at the Division of Dockets Management and on the Internet at *http://www.regulations.gov* approximately 30 days after the hearing.

For Registration to Attend and/or Participate in the Hearing: Seating at the hearing is limited. People interested in attending should submit electronic registration to Faith Dugan by close of business on September 15, 2008. Registration is free and will be on a first-come, first-served basis. Written or electronic comments will be accepted until December 2, 2008.

If you wish to make an oral presentation at the hearing, you must state your intention on your registration submission (see **ADDRESSES**). To speak, submit your name, title, business affiliation, address, telephone and fax numbers, and e-mail address. FDA has included questions for comment in section II of this document. You should also identify by number each question you wish to address in your presentation. FDA will do its best to accommodate requests to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter and the approximate time that each oral presentation is scheduled to begin.

If you need special accommodations because of a disability, please inform Faith Dugan, (see For Information on the Hearing Contact).

For Information on the Hearing Contact: Faith Dugan, Food and Drug Administration, 10903 New Hampshire Ave., rm. 6182, Silver Spring, MD 20993 , 301–796–3446, FAX: 301–847–4752, e-mail: Faith.Dugan@fda.hhs.gov.

Dated: August 27, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–20370 Filed 8–28–08; 11:15 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant