proposed by the Commission.'' [36] The Commission also continues to believe that ''such a system would present greater administrative, technical, and legal costs and complexities than the Commission's current proposal which does not require any proof or verification of that status.'' [37]

Another alternative would be reducing the current number of free area codes, but this approach might, among other things, require additional expenditures to process and service an increased number of paid subscriptions. In any event, reducing the number of free area codes may increase, rather than decrease, compliance costs for small businesses, if they had to pay for certain area codes that they can currently access for free.

Accordingly, the Commission believes its current proposal balances the interests of reducing the burden for small businesses to the greatest extent possible, while achieving the goal of covering the necessary costs to implement and enforce the Amended TSR.

Despite these conclusions, the Commission welcomes comment on any significant alternatives that would further minimize the impact on small entities, consistent with the objectives of the Telemarketing Act, the 2005 Appropriations Act, and the Implementation Act.

List of Subjects in 16 CFR Part 310

Telemarketing, Trade practices.

VII. Proposed Rule

Accordingly, for the reasons stated in the preamble, the Federal Trade Commission proposes to amend part 310 of title 16 of the Code of Federal Regulations as follows:

PART 310—TELEMARKETING SALES RULE

1. The authority citation for part 310 continues to read as follows:

Authority: 15 U.S.C. 6101–6108.

2. Revise § 310.8(c) and (d) to read as follows:

§ 310.8 Fee for access to the National Do Not Call Registry.

* * * * *

(c) The annual fee, which must be paid by any person prior to obtaining access to the National Do Not Call Registry, is $56 per area code of data accessed, up to a maximum of $15,400; *provided,* however, that there shall be no charge for the first five area codes of data accessed by any person, and *provided further,* that there shall be no charge to any person engaging in or causing others to engage in outbound telephone calls to consumers and who is accessing the National Do Not Call Registry without being required under this Rule, 47 CFR 64.1200, or any other federal law. Any person accessing the National Do Not Call Registry may not participate in any arrangement to share the cost of accessing the registry, including any arrangement with any telemarketer or service provider to divide the costs to access the registry among various clients of that telemarketer or service provider.

(d) After a person, either directly or through another person, pays the fees set forth in § 310.8(c), the person will be provided a unique account number which will allow that person to access the registry data for the selected area codes at any time for twelve months following the first day of the month in which the person paid the fee (''the annual period''). To obtain access to additional area codes of data during the first six months of the annual period, the person must first pay $56 for each additional area code of data not initially selected. To obtain access to additional area codes of data during the second six months of the annual period, the person must first pay $28 for each additional area code of data not initially selected. The payment of the additional fee will permit the person to access the additional area codes of data for the remainder of the annual period.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 05–8044 Filed 4–21–05; 8:45 am]

BILLING CODE 6750–01–P

[36] *See* 68 FR at 16,243 n.53.

[37] *Id.*

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 2005N–0147]

Sprout Safety Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to elicit information on the current science related to foodborne illness associated with the consumption of sprouts. In October 2004, FDA released a produce safety action plan entitled ''Produce Safety from Production to Consumption: 2004 Action Plan to Minimize Foodborne Illness Associated with Fresh Produce Consumption'' (Produce Action Plan). One item in the Produce Action Plan is to initiate rulemaking to minimize foodborne illness associated with the consumption of sprouted seeds. However, because of the complexities of the issues and the uncertainty about what the current science could support, FDA believes that it would be of value to hold a public meeting to gather information relevant to a possible regulation. We request that those who speak at the meeting, or otherwise provide FDA with their comments, focus on the questions relating to the microbial safety of seeds destined for sprouting and sprouted seeds set out in section II of this document.

DATES: The public meeting will be held in College Park, MD, on Tuesday, May 17, 2005, from 8:30 a.m. to 5 p.m. We request that everyone planning to attend the meeting register prior to the meeting. For security reasons and due to space limitations, we recommend that you register at least 5 business days before the meeting. You may register via the Internet and also by fax until close of business 5 days before the meeting, provided that space is available (see **FOR FURTHER INFORMATION CONTACT**). In addition to participating in the public meeting, you may submit written or electronic comments until July 18, 2005.

ADDRESSES: The public meeting will be held at the Harvey W. Wiley Federal Bldg., Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740–3835.

Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Amy L. Green, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 301–436–2025, FAX: 301–436–2651, or e-mail: *amy.green@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Since 1996, FDA has responded to 27 outbreaks of foodborne illness in the United States for which raw or lightly cooked sprouts were the confirmed or suspected vehicle for the illness. During

this 9-year period, sprouts accounted for 40 percent of all foodborne illness outbreaks associated with fresh produce and approximately 20 percent of the reported illnesses. The 27 outbreaks accounted for an estimated 1,636 reported cases of illness. Although the sprouts associated with these outbreaks have been primarily alfalfa, clover, or mung bean sprouts, FDA is concerned about the foodborne illness risk associated with all types of raw and lightly cooked sprouts. Thus, the agency has issued several advisories that warn consumers of the risks associated with consumption of raw or lightly cooked sprouts. The sprouts involved with the outbreaks have been generally of U.S. origin while the seeds from which the sprouts have been produced have been primarily of non-U.S. origin. To date, the causative agents have been *Salmonella* and *Escherichia coli* O157.

Sprouts present a special food safety challenge because the conditions that promote sprouting of the seed (e.g., temperature, humidity, available nutrients) also promote the growth of pathogens if pathogens are present. Seed appears to be the source of contamination in most of the foodborne illness outbreaks associated with sprout consumption. However, insanitary conditions at the sprouting facility appear to have exacerbated any seed contamination problems.

In October 1999, FDA issued a guidance entitled ''Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds.'' This guidance recommends preventive controls to assist all parties involved in the production of sprouts (seed producers, seed conditioners and distributors, and sprout producers) to reduce the risk of sprouts serving as a vehicle for foodborne illness. The guidance is available at *http://vm.cfsan.fda.gov/~dms/sprougd1.html*. Specific recommendations in this guidance include development and implementation of good agricultural practices and good manufacturing practices in the production and handling of seeds and sprouts, seed disinfection treatments, and microbial testing of spent irrigation water before the sprouts enter the food supply. At the same time, FDA issued a second guidance entitled ''Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water during Sprout Production,'' which contains recommendations to assist sprout producers in testing spent irrigation water for pathogens before sprout products enter the food supply. This second guidance is available at *http://vm.cfsan.fda.gov/~dms/sprougd2.html*. FDA also served as a technical consultant to the California Department of Health Services, who, in cooperation with the sprout industry, developed a video to advise the sprout industry on how to produce safer product.

For several years following release of FDA's guidance documents, foodborne illness outbreaks associated with alfalfa and clover sprouts appeared to diminish. In 2000, there was only one sprout-associated outbreak, compared to 6 outbreaks in 1999. Between 2000 and 2002, salmonellosis emerged as a foodborne illness associated with consumption of raw or lightly cooked mung bean sprouts. Recently, alfalfa sprouts remerged as a significant vehicle for foodborne illness, with 5 outbreaks in 2003 and 2 outbreaks in 2004.

We have observed a downward trend in the average number of cases associated with an outbreak since issuance of FDA's sprout guidances. Between 1996 and 1999, there were 14 outbreaks with 1,364 reported illnesses, an average of 97 cases per outbreak. Since FDA issued its sprout guidances, there have been 13 outbreaks with 272 reported illnesses, an average of 21 cases per outbreak.

FDA believes that the 1999 sprout guidances have had a significant positive effect on reducing both the number of outbreaks associated with sprouts and on the number of cases per outbreak. However, based on continuing outbreaks associated with raw and lightly cooked sprouts, the agency is concerned that further action may be needed to ensure sustained adoption of effective preventive controls by the seed and sprout industry as a whole. In October 2004, FDA released the Produce Action Plan. Now, FDA is considering whether a proposed regulation is needed to codify and expand on the existing sprout guidance.

FDA believes that a good first step to improving the safety of sprouts is to engage and solicit the views of other Government agencies at the Federal (Environmental Protection Agency, U.S. Department of Agriculture, Centers for Disease Control), state, and local levels, from industry, from consumer groups, and from the public generally about the current science relating to preventing or minimizing foodborne illness associated with the consumption of sprouts. The public meeting and period for submission of written comments are intended to provide that opportunity. FDA requests that comments presented at the public meeting or otherwise communicated to the agency focus on the questions set out in section II of this document.

II. Questions

1. What concepts or underlying principles should guide efforts to improve the safety of sprouts?

2. Which practices primarily contribute to the contamination with harmful pathogens of seeds used for sprouting? Which intervention strategies can help prevent, reduce, or control this contamination of seeds used for sprouting? Where appropriate, identify barriers to adopting effective preventive controls for this contamination, and, if possible, suggest mechanisms to overcome these barriers.

3. Which practices primarily contribute to the contamination with harmful pathogens of sprouts? Which intervention strategies can help prevent, reduce, or control the contamination of sprouts? Where appropriate, identify barriers to adopting effective preventive controls for this contamination, and, if possible, suggest mechanisms to overcome these barriers.

4. Do the preventive controls recommended in FDA's sprout guidances (*http://vm.cfsan.fda.gov/~dms/sprougd1.html* and *http://vm.cfsan.fda.gov/~dms/sprougd2.html*) need to be expanded or otherwise revised? If yes, please describe generally the areas that need expansion or other revision.

4. Although FDA's current recommendations address practices by all parties, efforts to promote adoption of effective preventive controls have focused largely on sprouting facilities. What can or should be done to increase the involvement of producers of seeds for sprouting and seed distributors to ensure the safety of sprouts?

5. Is a regulation likely to be an effective means of achieving the goal of minimizing foodborne illness associated with the consumption of sprouts? If not, what is likely to be an effective approach?

6. How can progress toward the overarching goal (to minimize foodborne illness associated with sprout consumption) be effectively measured?

7. There is broad variation within the seed and sprout industry, including variations in size of establishments, the types of seeds and sprouts produced, the practices used in production, and, possibly, variations in the vulnerability of a particular type of seed or sprout to microbial hazards or in the effectiveness of particular interventions. How, if at all, should the actions to improve the safety of seeds for sprouting be structured to take into account such variation? For example, should there be different sets of interventions for identifiable segments of the seed

industry? Similarly, how, if at all, should the actions to improve the safety of sprouts be structured to take into account such variation? For example, should there be different sets of interventions for identifiable segments of the sprouts industry? If yes, please describe.

8. Are there existing food safety systems or standards (such as international standards) that FDA should consider as part of the agency's efforts to minimize foodborne illness associated with the consumption of sprouts? Please identify these systems or standards and explain how their consideration might contribute to this effort.

III. Registration and Requests for Oral Presentations

You may register through FDA's Web site *http://www.cfsan.fda.gov/* and choose ''Public Meetings,'' by fax, or e-mail (see **FOR FURTHER INFORMATION CONTACT**). For security reasons and due to space limitations, we recommend that you register at least 5 days before the meeting. Registration will be accepted on a first-come basis; if you need special accommodations due to a disability, please inform the contact person at least 7 days in advance (see **FOR FURTHER INFORMATION CONTACT**). There is no registration fee for this public meeting, but early registration is encouraged because space is limited. In addition, early registration will expedite entry into the building and its parking area. If you require parking, please include the vehicle make and tag number, if known, on your registration form. Because the meeting will be held in a Federal building, you should also bring a photo ID and plan for adequate time to pass through security screening systems.

If you would like to make oral comments at the meeting, please specify your interest in speaking when you register. The amount of time for each oral presentation may be limited based upon the number of requests to speak. FDA encourages individuals or firms with relevant data or information to present such information at the meeting or in written comments to the record.

IV. Transcripts

A transcript will be made of the proceedings of the meeting. Transcripts of the meeting may be requested in writing from FDA's Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 30 working days after the meeting at a cost of 10 cents a page. The transcript of the public meeting and all comments submitted will be available for public examination at the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

V. Comments

In addition to presenting oral comments at the public meeting, interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the subject of this meeting. 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 the 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.

Dated: April 18, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–8103 Filed 4–19–05; 2:04 pm]

BILLING CODE 4160–01–S