excluding the Maryville, CA, Class E airspace area, and excluding that airspace within a 1-mile radius of the Richvale Airport.

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Issued in Los Angeles, California, on December 4, 1998.

Harvey R. Riebel,

Acting Manager, Air Traffic Division, Western-Pacific Region.

[FR Doc. 98–33440 Filed 12–16–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1042]

21 CFR Parts 10, 14, and 16

Proposed Revision of Administrative Practices and Procedures; Meetings and Correspondence; Public Calendars

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations relating to meetings and correspondence and the agency's public calendar. This proposed action would make FDA's procedures more concise and understandable to the public, minimize confusion about publicly available information concerning agency meetings and correspondence, provide for more effective disclosure of such information, and allow FDA to reallocate resources to areas of more urgent public health need. The agency is proposing these amendments in response to initiatives announced in the President's ''Regulatory Reinvention Initiative.''

DATES: Written comments by March 2, 1999.

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

FOR FURTHER INFORMATION CONTACT: Lisa L. Barclay, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, e-mail: ''lbarclay@bangate.fda.gov''.

SUPPLEMENTARY INFORMATION:

I. Background

On March 4, 1995, President Clinton issued a memorandum entitled ''Regulatory Reinvention Initiative.'' This memorandum, part of the reform of the Federal regulatory system, directed heads of departments and agencies to undertake a page-by-page review of their existing regulations and to eliminate or modify those that are outdated or otherwise in need of reform. As part of their review, agencies were requested to consider whether their regulations were obsolete and whether the intended goals of their regulations could be achieved in more efficient, less intrusive ways.

In response to the President's initiative, FDA conducted a comprehensive review of its existing regulations and identified those that could be eliminated or modified to create a more streamlined, less burdensome approach to government. Since the agency's resources are limited, it is in the best interest of the public health to ensure that resources are allocated to specific programs in a manner that is proportionate to their need.

In furtherance of the Reinventing Government initiatives, FDA is proposing to modify certain regulations pertaining to the public calendar and public meetings because such regulations are no longer effective in serving their intended purposes.

FDA procedures for maintaining a prospective calendar were originally established in 1977 to ensure that all persons outside the agency were given adequate notice of upcoming agency events and an accurate picture of the parties with whom agency officials were to meet. However, as explained in more detail as follows, the agency's experience has demonstrated that the maintenance of a prospective public calendar is no longer practical, workable, or beneficial to the public. Thus, the agency is now proposing to delete the prospective public calendar requirement from its regulations.

The agency is also proposing to revise its public calendar and public meetings regulations to make them more concise and useful to the public and industry by restructuring them, removing unduly burdensome provisions, and eliminating duplicative language and obsolete references. The proposed rule would reorganize the provisions so that information on certain topics is grouped together. The agency solicits comments and suggestions for further improvement of these regulations.

II. Specific Proposed Changes

A. Public Calendars

FDA regulations in § 10.100 (21 CFR 10.100) describe the agency's procedures for maintaining public calendars. Section 10.100 establishes requirements for the public calendars, including the agency personnel who are responsible for following the procedures, the requisite time period to be included in the calendars (4 weeks prospective and 1 week retrospective), and the locations where hard copies of the calendars are to be placed on public display.

1. Prospective Public Calendar

Current § 10.100(a) describes requirements for the maintenance of the prospective public calendar. This prospective calendar is to show public meetings, conferences, hearings, advisory committee meetings, seminars, and other public proceedings of FDA, as well as other significant public events involving FDA (e.g., Congressional hearings) for the upcoming 4 weeks. A hard copy of this prospective calendar is to be maintained in several places: (1) At the Dockets Management Branch; (2) in the Office of the Associate Commissioner for Public Affairs; (3) in a central place in each Center; and (4) in a central place in each field office.

In following the requirements for the prospective calendar, the agency has experienced significant difficulty in projecting calendar entries 4 weeks in advance. As a result, the information provided on the public calendar often is incomplete or incorrect. Frequently, the inclusion and later deletion of information in the prospective calendar creates confusion for the public. Furthermore, it is difficult to amend information in the prospective calendar after it has been placed on public display.

When FDA participates in meetings that are scheduled far in advance and involve a large number of people, such as public meetings or hearings held under 21 CFR part 15, the agency generally notifies the public through mechanisms other than the prospective calendar. Such mechanisms may include targeted mailings, notices on the World Wide Web (WWW), or publication in the **Federal Register**. Therefore, the prospective public calendar does not generally provide information to the public about large meetings that is not already available through other means. Occasionally, senior FDA officials participate in smaller public meetings with specific groups of outside participants, including members of industry, patient, consumer, or trade groups. These smaller meetings are often subject to last minute change, due to the highly unpredictable nature of the calendars of senior agency officials, making their inclusion on the prospective public calendar unduly burdensome to the agency. Thus, the agency tentatively

finds that the maintenance of a prospective public calendar is no longer practical, workable, or beneficial to the public.

To address these concerns, FDA is proposing that § 10.100(a) be removed. This action would eliminate the requirement for a 4-week prospective public calendar which, in turn, would allow agency staff to provide the most complete and accurate information possible to the public. The agency anticipates that members of the public who are interested in obtaining information regarding an open public meeting will not be significantly affected by this change because such information is already made available by FDA through mailings, notices on the WWW and in the **Federal Register**.

Furthermore, as discussed as follows, the agency is proposing to maintain its requirements for a retrospective public calendar. Through the retrospective calendar, interested persons would be able to obtain information about other meetings, including private meetings attended by FDA representatives, and to make requests (under the Freedom of Information Act) for publicly available documents relating to such meetings.

Ultimately, the proposed removal of the prospective calendar requirement would result in the devotion of less time and fewer agency resources to the public calendar, and the dissemination of more complete and more accurate information to the public, without diminishing the availability of essential information about upcoming meetings.

FDA regulations pertaining to public hearings before advisory committees (part 14 (21 CFR part 14)) and regulatory hearings before the agency (part 16 (21 CFR part 16)) include provisions that such hearings are to be included in the prospective public calendar (§§ 14.20(e) and 16.60(a)(3)). Since the agency is proposing to remove the prospective public calendar requirement in § 10.100(a), FDA also proposes to remove §§ 14.20(e) and 16.60(a)(3) as conforming amendments.

2. The Retrospective Calendar

Current § 10.100(b) requires FDA to maintain a 1-week retrospective public calendar. Section 10.100(b)(1) and (b)(2) describe the types of meetings that are to be listed on the retrospective calendar, including meetings with persons outside the executive branch and other significant events involving certain FDA officials. Current regulations do not require the retrospective public calendar to include reports of meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment in FDA), meetings with members of the press, or meetings with on-site contractors.

FDA is proposing to reorganize § 10.100(b)(1) and (b)(2) to clarify their meaning and to eliminate statements, e.g., references to ''house organs,'' that are no longer relevant to the day-to-day workings of the agency. The agency intends to list the types of meetings that are to be included in the retrospective public calendar in proposed § 10.100(a), which would state that entries are limited to: (1) Significant meetings with members of the Judiciary, representatives of Congress, or staffs of the congressional committees when the meetings relate to pending court cases, administrative hearings, or other regulatory actions or decisions; (2) significant meetings, conferences, seminars, and speeches; and (3) social events sponsored by the regulated industry. FDA would consider a meeting, conference, seminar, or speech to be ''significant'' if it addresses a matter that is of interest to a large number of people, or concerns a new policy or regulatory initiative. Under the proposed regulations, only meetings with persons outside of the executive branch of government would be included on the retrospective public calendar, and if there were no entries for a particular week, a statement to that effect would be issued in lieu of a calendar.

Current § 10.100(b)(2) states that the retrospective public calendar will include the date, person(s), and subject matter involved in any meeting that is reported on the calendar. If a large number of persons is involved, the name of each need not be specified, and if more than one FDA representative is in attendance, only the most senior official will report the meeting. The agency intends to maintain these requirements in proposed § 10.100(b).

Current § 10.100(b)(3) identifies the specific senior agency officials who are subject to the public calendar requirements. The current provision lists the Commissioner of Food and Drugs; Deputy Commissioner; Associate Commissioners; Executive and Special Assistants to the Commissioner; Director, National Center for Toxicological Research; Center Directors; and Chief Counsel for the Food and Drug Administration, or any representative of that office attending on behalf of the Chief Counsel, and their deputies. The agency is proposing to amend § 10.100(b)(3) to more accurately reflect the current personnel structure of the agency and to reduce the number of senior officials covered. The agency proposes that only the Commissioner of Food and Drugs, Deputy Commissioners, Center Directors, and the Chief Counsel be required to report meetings on the retrospective calendar because it has become unduly burdensome for assistants, deputies, and representatives of the agency's senior officials to report meetings. FDA anticipates that despite this limitation, meetings that are of greatest interest to the public will be reflected on the retrospective public calendar.

Current § 10.100(b)(4) states that a hard copy of the retrospective public calendar is to be kept in specific locations, including the Dockets Management Branch, the Office of the Associate Commissioner for Public Affairs, in each Center, and in each field office. FDA finds that keeping paper copies in all of these locations is not practical, and is unnecessarily burdensome to the agency. Consequently, the agency is proposing that § 10.100(b)(4) be amended to state that a copy will be available in the Dockets Management Branch, in the Office of the Associate Commissioner for Public Affairs and, to the extent feasible, on FDA's home page (http//www.fda.gov). Posting the retrospective calendar in such locations would enable FDA to provide access to the most recent version of the calendar to persons inside and outside the agency at all times. This proposed amendment would also reduce the paper burden on the agency.

B. Public Meetings

Section 10.65 (21 CFR 10.65) describes FDA's procedures for holding meetings and exchanging correspondence between agency representatives and persons outside FDA, including other Federal Government employees. Current § 10.65(b)(1) requires that the Commissioner give public notice of the time and place of open public meetings through the prospective public calendar, and gives the Commissioner the option of publishing notice of meetings. As discussed in section II.A.1 of this document, FDA is proposing to remove the provisions regarding the prospective public calendar in current § 10.100(a). The agency would need to amend § 10.65(b)(1) to conform with the removal of this regulation. FDA proposes that amended § 10.65(b)(1) state that the agency shall inform the public of the time and place of the meeting and of the matters to be discussed. This proposed change would give the agency the flexibility to choose the most effective manner of notifying the public of each public meeting. Such

notification may be achieved through notice in the **Federal Register**, posting on the WWW, or any other effective means of communication.

Current § 10.65(b)(3), 10.65(c), 10.65(d)(3), 10.65(e)(4), and 10.65(f)(2) require that the agency prepare a written memorandum summarizing the substance of all open public meetings initiated by FDA and certain public and private meetings with persons outside the agency. The agency may prepare a transcript or recording of an open public meeting initiated by FDA under § 10.65(b)(3) if the agency believes it would be useful. The current structure of the regulations may lead to confusion and FDA does not believe that the preparation of memoranda of meetings for the public meetings described previously is an efficient use of limited agency resources. Therefore, the agency is proposing to consolidate § 10.65(b)(3), (c), (d)(3), (e)(4), and (f)(2) in proposed § 10.65(e), which would require transcripts, recordings, or memoranda of meetings only when the agency determines that it would be useful. This determination will be left to the discretion of the senior agency official attending the meeting, taking into consideration the subject matter of the meeting, the public interest in the issue, and the value of using agency resources to prepare such transcripts, recordings, or memoranda.

Under current § 10.65(d), every person outside the Federal Government may request and obtain a private meeting with an FDA representative to discuss a matter. A person who wishes to attend a private meeting with FDA but is not permitted or able to attend may, under current § 10.65(d)(4), obtain a separate meeting with FDA to discuss the matter. FDA believes that it may be beneficial to meet with every individual outside the agency who requests a meeting, yet it simply is not feasible to guarantee a meeting to every such person. Consequently, FDA is proposing to amend § 10.65(d) and (d)(4) to state that any person may ''request'' a meeting with a representative of FDA, and that the agency will make a reasonable effort to accommodate such a request. Under these proposed amendments, an interested person would not necessarily ''obtain'' a meeting. These proposed amendments to § 10.65(d) and (d)(4) would enable the agency to better focus its energy and resources on matters involving public-health priorities.

Meetings with individuals outside the Federal Government that are initiated by FDA officials are addressed in current § 10.65(f). Under this provision, an FDA-initiated meeting that involves a large number of interested persons must be held as an open public conference or meeting. FDA is proposing to amend current § 10.65(f) to state that unless otherwise required by law, meetings may be public or private at FDA's discretion. FDA anticipates that significant meetings, i.e., those addressing matters that are of interest to a large number of people or that concern new policy or regulatory initiatives, generally will be held as open public meetings. Under this proposed revision, the determining factors for a public meeting would be the issue to be discussed and available agency resources, not the number of persons in attendance.

Current § 10.65(i) requires that FDA prepare a written memorandum of any meeting with a representative of Congress relating to a pending or potential investigation, inquiry, or hearing by a congressional committee or member of Congress. FDA proposes to remove this requirement because the agency generally does not believe that FDA resources should be expended to prepare such memoranda, given that any Congressional investigation or hearing typically involves many other publicly available documents, such as hearing transcripts, Congressional letters, and hearing testimony. Due to FDA's participation in a large number of meetings of this nature, the removal of § 10.65(i) would enable the agency to save a significant amount of resources that otherwise would be devoted to preparing such memoranda. Furthermore, if the agency were to determine that such documentation would be useful, a memorandum could be prepared under proposed § 10.65(e).

Current § 10.65(k) requires a log or summary to be maintained of all meetings between FDA and interested parties to implement the Radiation Control for Health and Safety Act of 1968 (Radiation Control Act) (42 U.S.C. 263l(a)(8)). Under section 19 of the Safe Medical Devices Act of 1990, Pub. L. 101–629, 104 Stat. 4511, 4530 (1990) the provisions of the Radiation Control Act were incorporated into section 540 of the act (21 U.S.C. 360qq). The agency proposes to reissue this provision in § 10.65(h) and to amend its text to reflect the change in statutory authority.

Conforming changes to §§ 10.30, 10.33, 10.35, and 10.40 are also being proposed to reflect the proposed changes in § 10.65.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121) and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Accordingly, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

V. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Request for Comments

Interested persons may, on or before March 2, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one 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 office above between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 10

Administrative practice and procedure, News media.

21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

21 CFR Part 16

Administrative practice and procedure.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 10, 14, and 16 be amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 continues to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 10.30 [Amended]

2. Section 10.30 *Citizen petition* is amended in paragraph (i)(6) by removing ''§ 10.65(h)'' and adding in its place ''§ 10.65''.

§ 10.33 [Amended]

3. Section 10.33 *Administrative reconsideration of action* is amended in paragraph (k)(6) by removing ''§ 10.65(h)'' and adding in its place ''§ 10.65''.

§ 10.35 [Amended]

4. Section 10.35 *Administrative stay of action* is amended in paragraph (h)(6) by removing ''§ 10.65(h)'' and adding in its place ''§ 10.65''.

§ 10.40 [Amended]

5. Section 10.40 *Promulgation of regulations for the efficient enforcement of the law* is amended in paragraph (g)(7) by removing ''§ 10.65(h)'' and adding in its place ''§ 10.65''.

6. Section 10.65 is revised to read as follows:

§ 10.65 Meetings and correspondence.

(a) In addition to public hearings and proceedings established under this part and other sections of this chapter, meetings may be held and correspondence may be exchanged between representatives of FDA and an interested person outside FDA on a matter within the jurisdiction of the laws administered by the Commissioner. Action on meetings and correspondence does not constitute final administrative action subject to judicial review under § 10.45.

(b) The Commissioner may conclude that it would be in the public interest to hold an open public meeting to discuss a matter (or class of matters) pending before FDA, in which any interested person may participate.

(1) The Commissioner shall inform the public of the time and place of the meeting and of the matters to be discussed.

(2) The meeting will be informal, i.e., any interested person may attend and participate in the discussion without prior notice to the agency unless the notice of the meeting specifies otherwise.

(c) Every person outside the Federal Government may request a private meeting with a representative of FDA in agency offices to discuss a matter. FDA will make reasonable efforts to accommodate such requests.

(1) The person requesting a meeting may be accompanied by a reasonable number of employees, consultants, or other persons with whom there is a commercial arrangement within the meaning of § 20.81(a) of this chapter. Neither FDA nor any other person may require the attendance of a person who is not an employee of the executive branch of the Federal Government without the agreement of the person requesting the meeting. Any person may attend by mutual consent of the person requesting the meeting and FDA.

(2) FDA will determine which representatives of the agency will attend the meeting. The person requesting the meeting may request but not require or preclude the attendance of a specific FDA employee.

(3) A person who wishes to attend a private meeting, but who is not invited to attend either by the person requesting the meeting or by FDA or who otherwise cannot attend the meeting, may request a separate meeting with FDA to discuss the same matter or an additional matter.

(d) FDA employees have a responsibility to meet with all segments of the public to promote the objectives of the laws administered by the agency. In pursuing this responsibility, the following general policy applies where agency employees are invited by persons outside the Federal Government to attend or participate in meetings outside agency offices as representatives of the agency.

(1) A person outside the executive branch may invite an agency representative to attend or participate in a meeting outside agency offices. The agency representative is not obligated to attend or participate, but may do so where it is in the public interest and will promote the objectives of the act.

(2) The agency representative may request that the meeting be open if that would be in the public interest. The agency representative may decline to participate in a meeting held as a private meeting if that will best serve the public interest.

(3) An agency representative may not knowingly participate in a meeting which is closed on the basis of gender, race, or religion.

(e) An official transcript, recording, or memorandum summarizing the substance of any meeting described in this section will be prepared by a representative of FDA when the agency determines that such documentation will be useful.

(1) Any other person who participates in a meeting described in this section may prepare and submit to FDA for inclusion in the administrative file a written memorandum summarizing the substance of the meeting.

(2) Memoranda of meetings prepared by FDA representatives or by any other person and all correspondence that relate to a matter pending before the agency will promptly be filed in the administrative file of the proceeding.

(f) Representatives of FDA may initiate a meeting or correspondence on any matter concerning the laws administered by the Commissioner. Unless otherwise required by law, meetings may be public or private at FDA's discretion.

(g) A meeting of an advisory committee is subject to the requirements of part 14 of this chapter.

(h) Under 21 U.S.C. 360qq(a)(8), a log or summary is to be made of all meetings between representatives of FDA and industry and other interested parties to implement the Electronic Product Radiation Control provisions of the act.

7. Section 10.100 is revised to read as follows:

§ 10.100 Public calendar.

(a) *Public calendar.* A public calendar will be prepared and made publicly available by FDA each week showing, to the extent feasible, significant events of the previous week, including significant meetings with persons outside the executive branch, that involve the representatives of FDA designated under paragraph (c) of this section.

(1) Public calendar entries will include:

(i) Significant meetings with members of the judiciary, representatives of Congress, or staffs of congressional committees when the meeting relates to a pending court case, administrative

hearing, or other regulatory action or decision;

(ii) Significant meetings, conferences, seminars, and speeches; and

(iii) Social events sponsored by the regulated industry.

(2) The public calendar will not include reports of meetings that would prejudice law enforcement activities (e.g., a meeting with an informant) or invade privacy (e.g., a meeting with a candidate for possible employment at FDA), meetings with members of the press, or meetings with on-site contractors.

(b) *Calendar entries.* The calendar will specify for each entry the date, person(s), and subject matter involved. If a large number of persons are in attendance, the name of each individual need not be specified. When more than one FDA representative is in attendance, the most senior agency official will report the meeting on the public calendar.

(c) *Affected persons.* The following FDA representatives are subject to the requirements of this section:

(1) Commissioner of Food and Drugs.

(2) Deputy Commissioners.

(3) Center Directors.

(4) Chief Counsel for the Food and Drug Administration.

(d) *Public display.* The public calendar will be placed on public display at the following locations:

(1) Dockets Management Branch.

(2) Office of the Associate Commissioner for Public Affairs.

(3) The FDA home page, to the extent feasible.

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

8. The authority citation for 21 CFR part 14 is revised to read as follows:

Authority: 5 U.S.C. App. 2; 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

§ 14.20 [Amended]

9. Section 14.20 *Notice of hearing before an advisory committee* is amended by removing paragraph (e).

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

10. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

§ 16.60 [Amended]

11. Section 16.60 *Hearing procedure* is amended by removing paragraph (a)(3).

Dated: December 10, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–33456 Filed 12–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 120

[Docket No. 97N–0511]

Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice: Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to January 16, 1999, the comment period for the proposal to require the application of hazard analysis and critical control point (HACCP) principles to the processing of fruit and vegetable juices and juice products (the juice HACCP proposal) that published in the **Federal Register** of April 24, 1998 (63 FR 20450). FDA is announcing the availability of the transcripts from two technical scientific workshops sponsored by FDA regarding implementation of the agency's warning statement requirement for fruit and vegetable juices and juice products. FDA is reopening the comment period for the juice HACCP proposal in order to receive comment on data and other information from the two technical scientific workshops. FDA is also reopening the comment period in order to receive comments and other information regarding the application of the 5-log pathogen reduction standard.

DATES: Written comments must be submitted by January 19, 1999.

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

FOR FURTHER INFORMATION CONTACT: Shellee A. Davis, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5023.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 24, 1998 (63 FR 20450), FDA proposed to adopt regulations to ensure the safe and sanitary processing of fruit and vegetable juices and juice products. In addition, in the **Federal Register** of July 8, 1998 (63 FR 37030), FDA published a final rule requiring that juice products not specifically processed to destroy harmful bacteria (i.e., processed to achieve a 5-log reduction in the most resistant pathogen of public health concern) bear a warning statement informing consumers of the potential risk of foodborne illness associated with the product (the warning statement rule). The compliance date for the warning statement rule was September 8, 1998, for apple juice and apple cider; the compliance date for juices other than apple juice or apple cider was November 5, 1998.

In the **Federal Register** of October 28, 1998 (63 FR 57594), FDA announced two technical scientific workshops to discuss and clarify issues related to the implementation of the warning statement rule for citrus juice products not specifically processed to destroy harmful bacteria. These workshops were held November 12, 1998, and November 19, 1998. Although the issues discussed in the workshops pertain to the implementation of the warning statement requirement, these issues also bear upon certain provisions of the HACCP proposal. FDA is announcing the availability of the transcripts from the two technical scientific workshops.

Interested persons were initially given until July 8, 1998, to comment on the HACCP proposal. On July 8, 1998 (63 FR 37057), in response to requests, the comment period was extended to August 7, 1998. FDA has decided to reopen the comment period to allow comment on data and other information that were presented at or developed as a result of these workshops to be included in the record of the HACCP rulemaking. In addition, FDA seeks comments on the application of the 5-log pathogen reduction standard. FDA requests comments on four specific topics: (1) Appropriate baselines for the calculation of the 5-log pathogen reduction; (2) feasible interventions or practices for the cultivation and harvest of fruits and vegetables, and acquisition of supplies and materials that may contribute to achieving a 5-log pathogen reduction; (3) feasible interventions for the production process that may contribute to achieving a 5-log pathogen reduction; and (4) acceptable methods for measuring and validating 5-log reductions.

To be considered, written comments must be received by January 16, 1999, by the Dockets Management Branch (address above). Two copies of any