A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product DIFFERIN Solution (adapalene). DIFFERIN Solution is indicated for the topical treatment of acne vulgaris. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for DIFFERIN Solution (U.S. Patent No. 5,212,303) from Centre International de Recherches Dermatologiques (CIRD), and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 24, 1996, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DIFFERIN Solution represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for DIFFERIN Solution is 2,814 days. Of this time, 1,651 days occurred during the testing phase of the regulatory review period, while 1,163 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective*: September 18, 1988. FDA has verified the applicant's claim that the date that the investigational new drug application became effective was on September 18, 1988.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act*: March 26, 1993. The applicant claims March 19, 1993, as the date the new drug application (NDA) for DIFFERIN Solution (NDA 20–338) was initially submitted. However, FDA records indicate that NDA 20–338 was submitted on March 26, 1993.

3. *The date the application was approved*: May 31, 1996. FDA has verified the applicant's claim that NDA 20–338 was approved on May 31, 1996.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 13 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before March 3, 1997 submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before July 1, 1997 for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 20, 1996.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 96–33381 Filed 12–31–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0449]

Current Science and Technology on Fresh Juices; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to February 3, 1997, the comment period on the notice that appeared in the Federal Register of November 27, 1996 (61 FR 60290). The notice announced a meeting to review the current science, including technological and safety factors, relating to fresh juices and to consider any measures necessary to provide safe fruit juices. The agency is taking this action in response to several requests for an extension of the comment period.

DATES: Written comments by February 3, 1997.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Catherine M. DeRoever, Center for Food Safety and Applied Nutrition (HFS–22), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4251, (FAX) 202–205–4970, (Internet) CMD@FDACF.SSW.DHHS.GOV.

SUPPLEMENTARY INFORMATION: In the Federal Register of November 27, 1996 (61 FR 60290), FDA requested information and data on: (1) Appropriate good manufacturing practices (GMP's) in juice processing; (2) identification of critical control points in juice processing under a Hazard Analysis and Critical Control Point System (HACCP); (3) whether pasteurization of fresh juices is appropriate or necessary; (4) sanitizers that are available to control pathogens of concern; (5) alternative available food additives that will ensure safety of fresh juices; (6) any new technologies/intervention strategies that are becoming available that appear to be effective in the control of *E. coli 0157:H7* or other pathogens of concern; and (7) the advice that should be given to consumers on fresh and other juice products. Interested persons were given until January 3, 1997, to submit written comments on the notice.

FDA received several requests for an extension of the comment period. After careful consideration, FDA has decided to extend the comment period to February 3, 1997, to facilitate the submission of relevant information on the above topics.

Interested persons may, on or before February 3, 1997, submit to the Dockets Management Branch (address above) written comments regarding this notice. 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.

Dated: December 26, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–33382 Filed 12–31–96; 8:45 am]

BILLING CODE 4160–01–F

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part at 60 FR 65350, December 19, 1995) is amended to reflect the realignment of the Office of Surveillance and Biometrics, Center for Devices and Radiological Health (CDRH), Office of Operations, in the Food and Drug Administration (FDA).

The functional statements of the Office of Surveillance and Biometrics have been modified to include participation in research and consultation on health economics and cost effectiveness methodology issues. In addition, program management activities have been elevated to the immediate office which will tighten the span of control within the Office.

Under section HF–B, Organization:

1. Delete the subparagraph *Program Management Staff (HFWH2), Center for Devices and Radiological Health (HFW),* in its entirety.

2. Delete the subparagraphs *Office of Surveillance and Biometrics (HFWH)* in their entirety and insert the following new subparagraphs under *Office of Surveillance and Biometrics (HFWH),* reading as follows:

Office of Surveillance and Biometrics. Advises, coordinates, and provides consultation to the Center Director and other Agency officials including the Commissioner on Center programs and policies concerning premarket review activities, postmarket management activities, surveillance and biometrics programs and activities, and regulatory matters for medical devices and radiological products.

Establishes policy for surveillance programs. Designs, develops, and implements a Center program to acquire device experience information; identifies and analyzes device problems; develops solution strategies to such problems; and tracks programs or solution implementations.

Provides statistical, epidemiological, and biometric services, and conducts research in support of the operating and scientific programs of the Center.

Represents the Center with other governmental agencies (Federal, State, and International), industry, and consumer organizations on issues related to the activities of the Office including postmarket management activities.

Provides consultation to Center Offices on health economics and cost effectiveness methodology issues pertaining to claims for medical devices.

Plans, develops, and implements office administrative support and services including program planning, financial management, extramural and collaborative efforts, procurement, travel, personnel administration, employee development and training, employee evaluations, recognition programs, property management, and facility space management.

3. Delete the subparagraphs *Issues Management Staff (HFWH1)* in their entirety and insert the following new subparagraphs under paragraph *Issues Management Staff (HFWH1), Center for Devices and Radiological Health (HFW),* reading as follows:

Issues Management Staff (HFWH1). Directs and monitors the analysis, resolution, development and solution implementation of postmarket issues; presents these issues to the CDRH, FDA, other agencies, and foreign governments as appropriate. Coordinates and disseminates information on developing issues and solution strategies within CDRH, FDA, and with other agencies and foreign governments as appropriate.

Provides and coordinates input on postmarket concerns and perspectives in support of Center initiatives, including encouragement and facilitation of the use of postmarket data available within the Center.

Develops and directs systems that track and monitor CDRH's postmarket surveillance issues; documents the recommendations, resolutions, and solution monitoring, and produces final reports for review by Center management.

Directs the preparation of issue papers and other reports or studies to promote the resolution of public health issues; coordinates these analyses with subject matter experts throughout CDRH, FDA and other Department of Health and Human Services agencies as required.

Represents CDRH's postmarketing surveillance concerns at industry, trade, professional, Agency, and international meetings. Develops and delivers speeches and papers, and acts as the Center's liaisons for postmarket issues.

4. Prior Delegations of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to positions of the affected organizations in effect prior to this date shall continue in effect in them or their successors.

Dated: November 27, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–33383 Filed 12–31–96; 8:45 am]

BILLING CODE 4160–01–F

Substance Abuse and Mental Health Services Administration

Notice of Meeting

Pursuant to Public Law 92–463, notice is hereby given of the following meeting of the SAMHSA Special Emphasis Panel I in January.

A summary of the meeting and a roster of the members may be obtained from: Ms. Dee Herman, Committee Management Liaison, SAMHSA Office of Extramural Activities Review, 5600 Fishers Lane, Room 17–89, Rockville, Maryland 20857. Telephone: (301)443–4783.

Substantive program information may be obtained from the individual named as Contact for the meeting listed below.

The meeting will include the review, discussion and evaluation of individual grant applications. These discussions could reveal personal information concerning individuals associated with the applications. Accordingly, this meeting is concerned with matters exempt from mandatory disclosure in Title 5 U.S.C. 552b(c)(6) and 5 U.S.C. App.2, Section 10(d).

Committee Name: SAMHSA Special Emphasis Panel I (SEP I).

Meeting Date: January 9, 1997, 9:00 a.m.–12:00 Noon.

Place: Doubletree Hotel—Room: Presidential II, 1750 Rockville Pike, Rockville, Maryland.

Closed: January 9, 1997, 9:00 a.m. until 12:00 Noon.

Panel: Cooperative Agreement with the National Association of State Alcohol and Drug Directors (NASADAD) GFA No. AS 97–0001.

Contact: Katie Baas, Room 17–89, Parklawn Building, Telephone: (301) 443–2592 and FAX: (301) 443–3437.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.