

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on October 29, 2001, from 8 a.m. to 5 p.m.

Location: Hilton DC North—Gaithersburg, Salons A, B, C, and D, 620 Perry Pkwy., Gaithersburg, MD.

Contact: Veronica J. Calvin, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-1243, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 12514. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will provide advice and recommendations on the types of data and/or labeling needed in premarket notification (510(k)) submissions for glucose test systems to address problems associated with using blood samples from alternate sites, such as the forearm, upper arm, thigh, calf, or base of the thumb. Background information, including the agenda and questions for the committee, will be available to the public on October 26, 2001, on the Internet at <http://www.fda.gov/cdrh/panelmtg.html>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by October 19, 2001. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon and between approximately 3 p.m. and 3:30 p.m. on October 29, 2001. Time allotted for each presentation may be limited. Those

desiring to make formal oral presentations should notify the contact person before October 19, 2001, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

FDA regrets that it was unable to publish this notice 15 days prior to the October 29, 2001, Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee meeting. Because the agency believes there is some urgency to bring these issues to public discussion and qualified members of the Clinical Chemistry and Clinical Toxicology Devices Panel of the Medical Devices Advisory Committee were available at this time, the Commissioner of Food and Drugs concluded that it was in the public interest to hold this meeting even if there was not sufficient time for the customary 15-day public notice.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 11, 2001.

Linda A. Suydam,

Senior Associate Commissioner.

[FR Doc. 01-26173 Filed 10-15-01; 9:31 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00E-1250]

Determination of Regulatory Review Period for Purposes of Patent Extension; Synercid; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of September 21, 2001 (66 FR 48692). The document determined the regulatory review period for Synercid and published the notice of that determination as required by law. The document published with an inadvertent error. This document corrects that error.

DATES: October 17, 2001.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Planning, and Legislation (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 01-23703, appearing on page 48690 in the **Federal Register** of Friday, September 21, 2001, the following correction is made: On page 48690, in the second column, "Docket No. 01E-1250]" is corrected to read "[Docket No. 00E-1250]".

Dated: October 10, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01-25998 Filed 10-16-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Indian Health Service (IHS).

ACTION: Request for Public Comment: 60-day notice; proposed collection; stakeholder satisfaction with IHS tribal consultation.

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, to provide a 60-day advance opportunity for public comment on a proposed information collection project, the Indian Health Service (IHS) is publishing for comment a summary of a proposed information collection to be submitted to the Office of Management and Budget (OMB) for review.

Proposed Collection

A voluntary survey will be conducted of elected leaders representing federally recognized tribes, and any board member or executive director authorized to represent a tribal organization or an urban Indian health program to assess the level of customer (stakeholder) satisfaction with the agency's tribal consultation process.

Title: Stakeholder Satisfaction with IHS Tribal Consultation.

Type of Information Collection

Request: New collection.

Form Number(s): None.

Need and Use of Information

Collection: The information gathered will be used by agency management and staff to establish baseline data, to identify strengths and weaknesses in the current consultation process, to assess how well the processes for consultation are working, to make improvements that are practical and feasible, and to provide feedback to local tribal officials, health boards, tribal organizations, urban Indian health programs and