ANDA No.	Drug
75–838	Propoxyphene Napsylate and Acetaminophen Tablets USP, 100 mg/650 mg
76–032	Methylphenidate HCl Exended-Release Tablets USP, 20 mg

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) and under authority delegated to the Director, Center for Drug Evaluation and Research (21 CFR 5.105(a)), approval of the ANDAs listed in the table of this document, and all amendments and supplements thereto, is withdrawn, effective August 29, 2005. Thereafter, distribution of the products in interstate commerce without approved applications is illegal and subject to regulatory action. Also, on the basis of the circumstances described in this document that led to the recall of the products and their subsequent removal from the market, the agency will remove the products from the agency's list of drug products with effective approvals, published under the title ''Approved Drug Products With Therapeutic Equivalence Evaluations.'' This document serves as notice of the removal of the products covered by the ANDAs listed in this document from the list of approved drug products. Distribution of these products in interstate commerce without approved applications is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the act (21 U.S.C. 355(a) and 331(d)).

Dated: August 15, 2005.

Steven Galson,

Director, Center for Drug Evaluation and Research.

[FR Doc. 05–17151 Filed 8–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Research Review Subcommittee of the Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a subcommittee of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Subcommittee: Research Review Subcommittee of the Cellular, Tissue and Gene Therapies 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 September 29, 2005, from 8 a.m. to 4 p.m.

Location: Holiday Inn Select, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Gail Dapolito or Sheila Langford, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 3014512389. Please call the Information Line for up-to-date information on this meeting.

Agenda: On September 29, 2005, the subcommittee will listen to presentations about the research program at the Office of Cellular, Tissue and Gene Therapies (OCTGT), Center for Biologics Evaluation and Research (CBER). The program is intended to provide dynamic, responsive, cutting edge research to contribute to OCTGT's regulatory mission and facilitate development of safe and effective biological products. The subcommittee will discuss the program and make recommendations to the Cellular Tissue and Gene Therapies Advisory Committee at a future open meeting of the full Committee. Information regarding CBER's scientific program is outlined in its Strategic Plan of 2004 and is available to the public on the Internet at: *http://www.fda.gov/cber/inside/mission.htm*. Information regarding FDA's Critical Path to New Medical Products is available to the public on the Internet at: *http://www.fda.gov/oc/initiatives/criticalpath/*.

Procedure: On September 29, 2005, from 8 a.m. to approximately 1:20 p.m., the meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the subcommittee. Written submissions may be made to the contact person by September 22, 2005. Oral presentations from the public will be scheduled between approximately 11:20 a.m. and 12:20 p.m. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person by September 22, 2005, 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.

Closed Subcommittee Deliberations: On September 29, 2005, from approximately 1:20 p.m. to 4 p.m. the meeting will be closed to the public. The meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)) and to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). The subcommittee will discuss internal research programs in OCTGT, CBER.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

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

Dated: August 18, 2005.

Scott Gottlieb,

Deputy Commissioner for Policy.

[FR Doc. 05–17149 Filed 8–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0312]

Draft Guidance for Industry on Abbreviated New Drug Applications: Impurities in Drug Products; Chemistry, Manufacturing, and Controls Information; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''ANDAs: Impurities in Drug Products; Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations on what chemistry, manufacturing, and controls information sponsors should include regarding reporting, identification, qualification, and setting acceptance criteria for impurities that are classified as degradation products in drug products when submitting an abbreviated new drug application (ANDA) or supplement to support changes in drug substance synthesis or process, formulation of the drug product, the manufacturing process, or components of the container/closure system.

DATES: Submit written or electronic comments on the draft guidance by November 28, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Devinder Gill, Center for Drug Evaluation and Research (HFD–630), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5845.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 5, 1999 (64 FR 516), FDA published the draft guidance for industry on ''ANDAs: Impurities in Drug Products.'' The draft guidance provided recommendations for including information in ANDAs and ANDA supplements about the reporting, identification, qualification of, and setting acceptance criteria for degradation products in drug products that are manufactured from drug substances produced by chemical synthesis.

FDA is announcing the availability of a revised draft guidance for industry entitled ''ANDAs: Impurities in Drug Products,'' which revises the January 5, 1999, draft guidance. The draft guidance is being revised to update information on listing of degradation products, setting acceptance criteria, and qualifying degradation products in conformance with our current thinking and the revision of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidance for industry on ''Q3B(R) Impurities in New Drug Products,'' published in November 2003. The draft guidance is also being revised to remove sections of the guidance containing recommendations that are no longer needed because they are addressed in the more recent Q3B(R).

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this draft guidance was approved under OMB Control No. 0910–0001.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on these topics. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: August 16, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–17150 Filed 8–26–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD17–05–0010]

Annual Certification of Cook Inlet Regional Citizen's Advisory Council (CIRCAC)

AGENCY: Coast Guard, DHS.

ACTION: Notice of recertification.

SUMMARY: Under the Oil Terminal and Tanker Environmental Oversight Act of 1990, the Coast Guard may certify on an annual basis an alternative voluntary advisory group in lieu of a regional citizens' advisory council for Cook Inlet, Alaska. This certification allows the advisory group to monitor the activities of terminal facilities and crude oil tankers under the Cook Inlet Program established by the statute. The purpose of this notice is to inform the public that the Coast Guard has recertified the alternative voluntary advisory group for Cook Inlet, Alaska.

DATES: This recertification is effective for the period from September 1, 2005 through August 31, 2006.

FOR FURTHER INFORMATION CONTACT: For general information regarding the CIRCAC or viewing material submitted to the docket, contact Rick Janelle, Seventeenth Coast Guard District, Marine Safety Division, (907) 463–2808.

SUPPLEMENTARY INFORMATION: In section 5002 of the Oil Pollution Act of 1990, cited as the Oil Terminal and Tanker Environmental Oversight and Monitoring Act of 1990 (the Act), Congress sought to foster the long-term partnership among industry, government, and local communities in overseeing compliance with the environmental concerns in the operation of terminal facilities and