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Draft Guidance for Industry on Abbreviated New Drug Applications: Impurities in Drug Products; Chemistry, Manufacturing, and Controls Information; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''ANDAs: Impurities in Drug Products; Chemistry, Manufacturing, and Controls Information.'' This draft guidance provides recommendations on what chemistry, manufacturing, and controls information sponsors should include regarding reporting, identification, qualification,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DATES: Submit written or electronic comments on the draft guidance by November 28, 2005.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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In the **Federal Register** of January 5, 1999 (64 FR 516), FDA published the draft guidance for industry on ''ANDAs: Impurities in Drug Products.'' The draft guidance provided recommendations for including information in ANDAs and ANDA supplements about the reporting, identification, qualification of, and setting acceptance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.

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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