of recently available data related to the safety of long-acting beta-agonist bronchodilators. On July 14, 2005, the committee will discuss the continued need for the essential use designations of prescription drugs for the treatment of asthma and chronic obstructive pulmonary disease under 21 CFR 2.125.

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 July 1, 2005. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on July 13, 2005, and between approximately 11 a.m. and 12 noon on July 14, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before July 1, 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.

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 La'Nise Giles at 301–827–7001 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: April 29, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–9229 Filed 5–9–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0062]

Draft Guidance for Industry on the Food and Drug Administration's ''Drug Watch'' for Emerging Drug Safety Information; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''FDA's 'Drug Watch' for Emerging Drug Safety Information.'' This document provides guidance about how FDA intends to develop and disseminate important emerging drug safety information concerning marketed drug products to healthcare professionals and patients. This information will appear on an FDA Web page to be called the ''Drug Watch.''

DATES: Submit written or electronic comments on the draft guidance by August 8, 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: Deborah J. Henderson, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20855, 301–594–5400.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''FDA's 'Drug Watch' for Emerging Drug Safety Information.'' This document provides guidance about how FDA intends to develop and disseminate important emerging drug safety information concerning marketed drug products to healthcare professionals and patients.

In the last several months, members of patient groups, the medical community, and Congress have raised concerns regarding the way in which FDA has handled certain drug safety issues, most recently in connection with the withdrawal of Vioxx from the market and with the management of the risks of suicide associated with pediatric use of antidepressants. As a result, FDA is carefully evaluating its institutional approach to drug safety issues, focusing especially on the ways in which the agency responds to new safety concerns and resolves scientific disagreements about product safety between agency components. As part of this process, FDA is also reexamining its risk communication program, including how and when we communicate significant emerging safety information to healthcare professionals and patients.[1]

FDA has long provided information on drug risks and benefits to healthcare professionals and patients. In the past, we provided that information when we were certain of its significance or it prompted a regulatory action, such as a labeling change. We have now decided to make important drug safety information available to healthcare professionals and patients in a new format and earlier than we have in the past. This information will appear on an FDA Web page called the ''Drug Watch.''

II. The Drug Watch Program

The goal of the Drug Watch program is to ensure that patients and healthcare professionals have quick access to the most up-to-date and accurate product information available in an easily accessible form. The Drug Watch Web page will post significant emerging safety information that FDA has received about certain drugs (or classes of drugs) while the agency continues to actively evaluate the information. The Drug Watch page is not intended to be a list of drugs that are particularly risky or dangerous for use; listing of a drug on the Drug Watch should not be construed as a statement by FDA that the drug is dangerous or that it is inappropriate for use. All drugs have risks, and prescribers must balance the risks and benefits of a drug when making judgments about an individual patient's therapy. However, sometimes after a drug is approved, rare but serious new side effects emerge as the drug is more widely used or is prescribed for off-label uses. Sometimes these emerging risks appear to be life-threatening, while in other cases they may appear to be less serious. In most instances, however, there is a period of uncertainty while FDA and the drug's sponsor evaluate new, emerging safety information to determine whether the safety concern in fact relates to the drug, and whether regulatory or other action is appropriate. The purpose of the Drug Watch is to provide a forum from which FDA can communicate emerging safety information to the public while we

[1] For information about the other steps FDA is taking see *http://www.fda.gov/bbs/topics/news/2004/NEW01131.html*.

continue to evaluate that information. We intend to work as quickly as possible to assess and address the safety issues identified on the Drug Watch, and we will continue to communicate important information about drug risks that are known with greater certainty using traditional means, such as public health advisories. Our goal with the Drug Watch is to share emerging safety information before we have fully determined its significance or taken final regulatory action so that patients and healthcare professionals will have the most current information concerning the potential risks and benefits of marketed drug products.

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 FDA's Drug Watch for emerging drug safety information. 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.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of mailed 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. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. 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: May 4, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9297 Filed 5–5–05; 3:42 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD 17–05–005]

Prince William Sound Regional Citizens' Advisory Committee Charter Renewal

AGENCY: Coast Guard, DHS.

ACTION: Notice of recertification.

SUMMARY: The purpose of this notice is to inform the public that the Coast Guard has recertified the Prince William Sound Regional Citizens' Advisory Council (PWSRCAC) as an alternative voluntary advisory group for Prince William Sound, Alaska. This certification allows the PWSRCAC to monitor the activities of terminal facilities and crude oil tankers under the Prince William Sound Program established by statute.

DATES: This recertification is effective for the period from March 1, 2005, through February 28, 2006.

FOR FURTHER INFORMATION CONTACT: Commander, Seventeenth Coast Guard District, Marine Safety Division, Response Branch by phone at (907) 463–2804, or by mail at P.O. Box 25517; Juneau, Alaska 99802.

SUPPLEMENTARY INFORMATION:

Background and Purpose

As part of the Oil Pollution Act of 1990, Congress passed the Oil Terminal and Oil Tanker Environmental Oversight and Monitoring Act of 1990 (the Act), 33 U.S.C. 2732, to foster a long-term partnership among industry, government, and local communities in overseeing compliance with environmental concerns in the operation of crude oil terminals and oil tankers.

On October 18, 1991, the President delegated his authority under 33 U.S.C 2732 (o) to the Secretary of Transportation in Executive Order 12777, section 8(g) (*see* 56 FR 54757; October 22, 1991) for purposes of certifying advisory councils, or groups, subject to the Act. On March 3, 1992, the Secretary redelegated that authority to the Commandant of the USCG (*see* 57 FR 8582; March 11, 1992). The Commandant redelegated that authority to the Chief, Office of Marine Safety, Security and Environmental Protection (G–M) on March 19, 1992 (letter #5402).

On July 7, 1993, the USCG published a policy statement, 58 FR 36504, to clarify the factors that shall be considered in making the determination as to whether advisory councils, or groups, should be certified in accordance with the Act.

The Assistant Commandant for Marine Safety and Environmental Protection (G–M), redelegated recertification authority for advisory councils, or groups, to the Commander, Seventeenth Coast Guard District on February 26, 1999 (letter #16450).

On September 16, 2002, the USCG published a policy statement, 67 FR 58440, that changed the recertification procedures such that applicants are required to provide the USCG with comprehensive information every three years (triennially). For each of the two years between the triennial application procedure, applicants submit a letter requesting recertification that includes a description of any substantive changes to the information provided at the previous triennial recertification.

Discussion of Comments

The January 12, 2005, the USCG published a Notice of Application Submission Deadline; Request for Comments for Recertification of Prince William Sound Regional Citizens' Advisory Council in the **Federal Register** (70 FR 2181). We received 17 letters commenting on the proposed action. No public meeting was requested, and none was held. Of the 17 comments received, 16 were positive. These letters in support of the recertification consistently cited PWSRCAC's broad representation of the respective community's interests, appropriate actions to keep the public informed, improvements to both spill response preparation and spill prevention, and oil spill industry monitoring efforts that combat complacency—as intended by the Act.

The USCG received one comment in opposition to PWSRCAC's recertification. The Native Village of Eyak (NVE) recommended the Coast Guard de-certify the PWSRCAC because it neither represents the NVE, nor can it afford representation to the NVE through membership on the PWSRCAC Board of Directors. The NVE stated that a separate Tribal oversight group should be created. They further stated that advisory group funding should be directed to this Tribal oversight group, and that this group would exist in addition to, not in place of, the PWSRCAC. NVE has twice before voiced this opposition in letters of comment on PWSRCAC's 2001 and 2002 recertification. Commandant, Seventeenth Coast District answered NVE's opposition, with direct responses dated September 7, 2001, and July 11, 2002. For the purpose of public record, those responses are provided here: