

device manufacturers with the integration of risk management concepts into their quality management system by providing practical explanations and examples. It is based on general principles of a quality management system and general principles of a risk management system and not on any particular standard or regulatory requirement. This document has general applicability to quality management systems for organizations providing medical devices. This document will discuss risks related to product safety, rather than other business risks. The integration of risk management into the quality management system is applicable to all stages of the life cycle of a medical device. This guidance does not suggest particular methods of implementation and therefore should not be used to assess or audit compliance with regulatory requirements.

Study Group 4 was initially tasked with the responsibility of developing auditing guidelines. These guidelines are intended to provide guidance on regulatory auditing of quality systems of medical device manufacturers. As a result of their efforts, this group has developed SG4/N30R6 (proposed document) entitled "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers—Part 2: Regulatory Auditing Strategy." This document is intended to be used by regulatory auditing organizations and auditors as a guide for conducting medical device quality systems audits based on the process approach to quality management of ISO 13485:2003. Additional regulatory requirements and guidance will need to be considered, depending on the regulatory authorities who will receive and use the audit report. This guidance document applies to initial audits and to surveillance audits as they are defined in "Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers—Part I: General Requirements (SG4/N28R2)"—including the supplements—developed by GHTF Study Group 4 as a guide for auditing organizations.

These documents represent recommendations from the GHTF Study Groups and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions.

## II. Electronic Access

Persons interested in obtaining copies of these draft documents may also do so using the Internet. Updated on a regular basis, the CDRH home page includes

device safety alerts (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video-oriented conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. Information on the GHTF may be accessed at <http://www.ghtf.org>.

## III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding any of these documents. 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 and with the full title of these documents. The draft documents and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 4, 2004.

**Lillian J. Gill,**

*Acting Deputy Director, Center for Devices and Radiological Health.*

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**BILLING CODE 4160-01-5**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0050]

#### Over-the-Counter Drug Products; Safety and Efficacy Review; Additional Dandruff Control Ingredient

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of eligibility; request for data and information.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a call-for-data for safety and effectiveness information on the following conditions as part of FDA's ongoing review of over-the-counter (OTC) drug products: Piroctone olamine, 0.05 percent to 0.5 percent and 0.1 percent to 1.0 percent, for use as a dandruff control single active ingredient in leave-on and rinse-off dosage forms, respectively. FDA has reviewed a time and extent application (TEA) for these conditions and determined that they are eligible for consideration in its OTC drug monograph system. FDA will evaluate the submitted data and information to determine whether these conditions can

be generally recognized as safe and effective (GRAS/E) for their proposed OTC use.

**DATES:** Submit data, information, and general comments by May 18, 2004.

**ADDRESSES:** Submit written comments, data, and information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments, data, and information to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Michael L. Koenig, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

## SUPPLEMENTARY INFORMATION:

### I. Background

In the **Federal Register** of January 23, 2002 (67 FR 3060), FDA published a final rule establishing criteria and procedures for additional conditions to become eligible for consideration in the OTC drug monograph system. These criteria and procedures, codified in § 330.14 (21 CFR 330.14), permit OTC drugs initially marketed in the United States after the OTC drug review began in 1972 and OTC drugs without any marketing experience in the United States to become eligible for FDA's OTC drug monograph system. The term "condition" means an active ingredient or botanical drug substance (or a combination of active ingredients or botanical drug substances), dosage form, dosage strength, or route of administration, marketed for a specific OTC use (§ 330.14(a)). The criteria and procedures also permit conditions that are regulated as cosmetics or dietary supplements in foreign countries but that would be regulated as OTC drugs in the United States to become eligible for the OTC drug monograph system.

Sponsors must provide specific data and information in a TEA to demonstrate that the condition has been marketed for a material time and to a material extent to become eligible for consideration in the OTC drug monograph system. When the condition is found eligible, FDA publishes a notice of eligibility and request for safety and effectiveness data for the proposed OTC use. The TEA that the agency reviewed (Ref. 1) and FDA's evaluation of the TEA (Ref. 2) have been placed on public display in the Division of Dockets Management (see **ADDRESSES**) under the docket number found in brackets in the heading of this document. Information deemed confidential under 18 U.S.C. 1905, 5

U.S.C. 552(b), or 21 U.S.C. 331(j) was deleted from the TEA before it was placed on public display.

## II. Request for Data and Information

The conditions piroctone olamine, 0.05 percent to 0.5 percent and 0.1 percent to 1.0 percent, as a dandruff control single active ingredient in leave-on and rinse-off dosage forms, respectively, will be evaluated for inclusion in the monograph for OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis (21 CFR part 358, subpart H). Accordingly, FDA invites all interested persons to submit data and information, as described in § 330.14(f), on the safety and effectiveness of these conditions for FDA to determine whether they can be GRAS/E and not misbranded under recommended conditions of OTC use. The TEA did not include an official or proposed United States Pharmacopeia-National Formulary (USP-NF) drug monograph for piroctone olamine. According to § 330.14(i), an official or proposed USP-NF monograph for piroctone olamine must be included as part of the safety and effectiveness data for this ingredient. Interested parties should provide an official or proposed USP-NF monograph and safety and effectiveness data for both leave-on and rinse-off dosage forms containing this ingredient.

Interested persons should submit comments, data, and information to the Division of Dockets Management (see **ADDRESSES**) by May 18, 2004. Three copies of all comments, data, and information are to be submitted. Individuals submitting written information or anyone submitting electronic comments may submit one copy. Submissions are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by supporting information. Received submissions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. Information submitted after the closing date will not be considered except by petition under 21 CFR 10.30.

## III. Marketing Policy

Under § 330.14(h), any product containing the conditions for which data and information are requested may not be marketed as an OTC drug in the United States at this time unless it is the subject of an approved new drug application or abbreviated new drug application.

## IV. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. TEA for piroctone olamine submitted by Keller and Heckman LLP on behalf of Clariant GmbH., dated July 11, 2003.

2. FDA's evaluation and comments on the TEA for piroctone olamine.

Dated: February 10, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-3413 Filed 2-17-04; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

#### Open Meeting of the Federal Interagency Committee on Emergency Medical Services (FICEMS)

**AGENCY:** Federal Emergency Management Agency (FEMA), Emergency Preparedness and Response Directorate, Department of Homeland Security.

**ACTION:** Notice of open meeting.

**SUMMARY:** FEMA announces the following open meeting.

*Name:* Federal Interagency Committee on Emergency Medical Services (FICEMS).

*Date of Meeting:* March 4, 2004.

*Place:* Building J, Room 103, National Emergency Training Center (NETC), 16825 South Seton Avenue, Emmitsburg, Maryland 21727.

*Times:* 9 a.m.—FICEMS Ambulance Safety Subcommittee; 10:30 a.m.—Main FICEMS Meeting; 1 p.m.—FICEMS Counter-Terrorism Subcommittee and the Performance Technology Subcommittee.

*Proposed Agenda:* Review and submission for approval of previous FICEMS Committee Meeting Minutes; Ambulance Safety Subcommittee and Counter-terrorism Subcommittee report; Action Items review; presentation of member agency reports; and reports of other interested parties.

**SUPPLEMENTARY INFORMATION:** This meeting will be open to the public with limited seating available on a first-come, first-served basis. See the Response and Security Procedures below.

*Response Procedures:* Committee Members and members of the general public who plan to attend the meeting should contact Ms. Patti Roman, on or

before Tuesday, March 2, 2004, via mail at NATEK Incorporated, 21355 Ridgetop Circle, Suite 200, Dulles, Virginia 20166-8503, or by telephone at (703) 674-0190, or via facsimile at (703) 674-0195, or via e-mail at [proman@natekinc.com](mailto:proman@natekinc.com). This is necessary to be able to create and provide a current roster of visitors to NETC Security per directives.

*Security Procedures:* Increased security controls and surveillance are in effect at the National Emergency Training Center. All visitors must have a valid picture identification card and their vehicles will be subject to search by Security personnel. All visitors will be issued a visitor pass which must be worn at all times while on campus. Please allow adequate time before the meeting to complete the security process.

*Conference Call Capabilities:* If you are not able to attend in person, a toll free number has been set up for teleconferencing. The toll free number will be available from 9 a.m. until 4 p.m. Members should call in around 9 a.m. The number is 1-800-320-4330. The FICEMS conference code is "430746#."

*FICEMS Meeting Minutes:* Minutes of the meeting will be prepared and will be available upon request 30 days after they have been approved at the next FICEMS Committee Meeting on June 3, 2004. The minutes will also be posted on the United States Fire Administration Web site at <http://www.usfa.fema.gov/ems/ficems.htm> within 30 days after their approval at the June 3, 2004, FICEMS Committee Meeting.

Dated: January 20, 2004.

**R. David Paulison,**

*U.S. Fire Administrator, Director of the Preparedness Division.*

[FR Doc. 04-3434 Filed 2-17-04; 8:45 am]

**BILLING CODE 9110-17-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[AK-921-1410-BK-P]

#### Notice for Publication; Filing of Plat of Survey; Alaska

1. A plat of survey for the following described lands was officially filed in the Alaska State Office, Anchorage, Alaska, on the date indicated:

A plat representing the corrective dependent resurvey of line 1-2 of the Nome Townsite, Amended U.S. Survey No. 451; the dependent resurvey of line 4-5 of the Nome Townsite, Amended