DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0404]

Guidance for Industry on Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use—Small Entity Compliance Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for small business entities entitled "Organ Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Use—Small Entity Compliance Guide." This guidance is intended to help small businesses understand and comply with FDA's regulation entitled "Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Use; Final Monograph" (74 FR 19385, April 29, 2009).[1] The guidance describes the organ-specific labeling requirements in plain language and provides answers to common questions on how to comply with the rule. This guidance was prepared in accordance with the Small Business Regulatory Fairness Act.

DATES: Submit either electronic or written comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Arlene Solbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5426, Silver Spring, MD 20993–0002, 301–796–2090.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a new guidance for small business entities entitled "Organ-Specific Warnings: Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use—Small Entity Compliance Guide." This small entity compliance guide applies to over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic (IAAA) drug products that contain acetaminophen or nonsteroidal anti-inflammatory drug ingredients (NSAIDs). The labeling of those products must include specific warnings about the risks of liver injury when using acetaminophen, and stomach bleeding when using nonsteroidal NSAIDs, as well as related information appearing on the principal display panel. Manufacturers must be in compliance with the rule beginning on April 29, 2010.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on organ-specific labeling requirements for OTC IAAA drug products. 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**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

[1] As amended November 25, 2009 (74 FR 61512).

Dated: August 5, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–20252 Filed 8–16–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices Advisory Committee (HICPAC)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting of the aforementioned committee:

Time and Date: 1:30 p.m.–3 p.m., September 8, 2010.

Place: Teleconference.

Status: Open to the public. Teleconference access limited only by availability of telephone ports. To participate in the teleconference please dial 1–888–324–7115 and enter conference code 5959790.

Purpose: The Committee is charged with providing advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; the Director, CDC; and the Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), regarding: (1) The practice of hospital infection control; strategies for surveillance, prevention, and control of infections (*e.g.,* nosocomial infections), antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters To Be Discussed: The agenda will include a follow up discussion on the *Draft Guideline for the Prevention and Control of Norovirus Gastroenteritis Outbreaks in Healthcare Settings.* Materials for the call will be available on the HICPAC Web site, *http://www.cdc.gov/hicpac,* no later than September 6, 2010.

Agenda items are subject to change as priorities dictate.

Contact Person For More Information: Michelle King, HICPAC, Division of Healthcare Quality Promotion, NCEZID, CDC, 1600 Clifton Road, NE., Mailstop A–07, Atlanta, Georgia 30333; *E-mail: HICPAC@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.