DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 343

[Docket No. 77N–0941]

RIN 0910–AA01

Internal Analgesic, Antipyretic, and Antirheumatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of the Tentative Final Monograph, and Related Labeling; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until September 2, 2003, the comment period on the agency's proposal to amend the tentative final monograph (TFM) for over-the-counter (OTC) internal analgesic, antipyretic, and antirheumatic (IAAA) drug products to include ibuprofen as a generally recognized safe and effective analgesic/antipyretic active ingredient for OTC use and to amend its regulations to include consistent allergy warnings for OTC IAAA drug products containing nonsteroidal antiinflammatory active ingredients. The proposal was published in the **Federal Register** of August 21, 2002 (67 FR 54139). FDA is taking this action in response to a request for an extension of 90 days for the submission of comments on the proposed rule. The comment period for this information closed on November 19, 2002.

DATES: Submit written or electronic comments by September 2, 2003.

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

FOR FURTHER INFORMATION CONTACT: Ida I. Yoder, 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 August 21, 2002 (67 FR 54139), FDA published a proposed rule to amend the TFM for OTC IAAA drug products to include ibuprofen as a generally recognized safe and effective analgesic/antipyretic active ingredient for OTC use and to amend its regulations to include consistent allergy warnings for OTC IAAA drug products that contain nonsteroidal antiinflammatory active ingredients.

The proposed rule was in response to a citizen petition and a comment to that petition and is part of FDA's ongoing review of OTC drug products. Based on the information submitted and other relevant information, FDA determined that ibuprofen in a 200-milligram (mg) tablet formulation for use in adults and children 12 years of age and older, at a maximum daily dose of 1,200 mg, qualifies as safe and effective for inclusion in an OTC drug monograph when labeled with adequate warnings and directions for use. Therefore, FDA proposed to include ibuprofen 200 mg, in tablet formulation, in 21 CFR 343.10(g) as a safe and effective ingredient for the relief of pain and fever in adults and children 12 years of age and older and to include specific warnings and directions for use in 21 CFR 343.50(c) and (d).

The agency also tentatively concluded that, for consistency, the ''Allergy alert'' and additional allergy warning statements required for certain OTC NSAID IAAA drug products should be extended to all such products, whether marketed under an OTC drug monograph or an NDA/ANDA. These standardized allergy alert and warning statements (in proposed § 201.324) would provide the following information:

(a) ''**Allergy alert**: [insert name of active ingredient (first letter of first word for ingredient in uppercase)] may cause a severe allergic reaction which may include:

- hives.
- facial swelling.
- asthma (wheezing).
- shock''.

(b) ''**Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer'' (This statement appears as the first warning under the subheading ''Do not use.'')

(c) ''**Stop use and ask a doctor if** an allergic reaction occurs. Seek medical help right away.'' (These statements appear as the first warning under the subheading ''Stop use and ask a doctor if.'')

On October 11, 2002, FDA received a request (Ref. 1) for an extension of 90 days for submission of comments on the proposed rule. The comment stated that it had delayed its response to the proposal so that consideration could be given to the impact of FDA's Nonprescription Drug Advisory Committee (NDAC) discussions on the labeling of all OTC IAAA drug products, including ibuprofen, at its September 19 and 20, 2002, meeting. Therefore, the comment stated that it needed additional time to evaluate and comment on labeling suggestions that arose from the NDAC meeting and to review the preclinical and clinical safety data that the agency used to support label warning statements. Further, the comment stated that it was considering conducting consumer research on information relevant to crafting an appropriate OTC label for these products.

FDA has carefully considered the request and acknowledges that additional time may be beneficial to fully evaluate and respond to the issues. FDA considers an extension of time for comments to be in the public interest. Therefore, the agency is providing additional time for comments by reopening the comment period for 90 days from the date of this notice.

II. Request for Comments

Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Reference

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

1. Comment No. EXT1.

Dated: May 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–13914 Filed 6–3–03; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 194

[FRL–7507–5]

Waste Characterization Program Documents Applicable to Transuranic Radioactive Waste From the Hanford Site for Disposal at the Waste Isolation Pilot Plant

AGENCY: Environmental Protection Agency.