## 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]

**BILLING CODE 4160–01–S**

## 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.

**ACTION:** Notice of availability; opening of public comment period.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing the availability of, and soliciting public comments for 30 days on, Department of Energy (DOE) documents applicable to characterization of transuranic (TRU) radioactive waste at the Hanford site proposed for disposal at the Waste Isolation Pilot Plant (WIPP). The documents (Item II–A2–44, Docket A–98–49) are available for review in the public dockets listed in **ADDRESSES.** EPA will conduct an inspection of waste characterization systems and processes at Hanford to verify that the site can characterize transuranic waste in accordance with EPA's WIPP compliance criteria. EPA will perform this inspection the week of June 16, 2003.

**DATES:** EPA is requesting public comment on the documents. Comments must be received by EPA's official Air Docket on or before July 7, 2003.

**ADDRESSES:** Comments should be submitted to: EPA Docket Center (EPA/DC), Air and Radiation Docket, Docket No. A–98–49, EPA West, Mail Code 6102T, 1200 Pennsylvania Avenue, NW., Washington, DC 20460. The DOE documents are available for review in the official EPA Air Docket in Washington, DC, Docket No. A–98–49, Category II–A2, and at the following three EPA WIPP informational docket locations in New Mexico: in Carlsbad at the Municipal Library, Hours: Monday–Thursday, 10 a.m.–9 p.m., Friday–Saturday, 10 a.m.–6 p.m., and Sunday, 1 p.m.–5 p.m.; in Albuquerque at the Government Publications Department, Zimmerman Library, University of New Mexico, Hours: vary by semester; and in Santa Fe at the New Mexico State Library, Hours: Monday–Friday, 9 a.m.–5 p.m.

As provided in EPA's regulations at 40 CFR part 2, and in accordance with normal EPA docket procedures, if copies of any docket materials are requested, a reasonable fee may be charged for photocopying. Air Docket A–98–49 in Washington, DC, accepts comments sent electronically or by fax (fax: 202–566–1741; e-mail: *a-and-r-docket@epa.gov*).

**FOR FURTHER INFORMATION CONTACT:** Ms. Rajani D. Joglekar, Office of Radiation and Indoor Air, (202) 564–7734. You can also call EPA's toll-free WIPP Information Line, 1–800–331–WIPP or visit our Web site at *http://www.epa/gov/radiation/wipp*.

**SUPPLEMENTARY INFORMATION:**

**Background**

DOE is developing the WIPP near Carlsbad in southeastern New Mexico as a deep geologic repository for disposal of TRU radioactive waste. As defined by the WIPP Land Withdrawal Act (LWA) of 1992 (Public Law 102–579), as amended (Public Law 104–201), TRU waste consists of materials containing elements having atomic numbers greater than 92 (with half-lives greater than twenty years), in concentrations greater than 100 nanocuries of alpha-emitting TRU isotopes per gram of waste. Much of the existing TRU waste consists of items contaminated during the production of nuclear weapons, such as rags, equipment, tools, and sludges.

On May 13, 1998, EPA announced its final compliance certification decision to the Secretary of Energy (published May 18, 1998, 63 FR 27354). This decision stated that the WIPP will comply with EPA's radioactive waste disposal regulations at 40 CFR part 191, subparts B and C.

The final WIPP certification decision includes conditions that (1) prohibit shipment of TRU waste for disposal at WIPP from any site other than the Los Alamos National Laboratory (LANL) until the EPA determines that the site has established and executed a quality assurance program, in accordance with §§ 194.22(a)(2)(i), 194.24(c)(3), and 194.24(c)(5) for waste characterization activities and assumptions (Condition 2 of appendix A to 40 CFR part 194); and (2) prohibit shipment of TRU waste for disposal at WIPP from any site other than LANL until the EPA has approved the procedures developed to comply with the waste characterization requirements of § 194.22(c)(4) (Condition 3 of appendix A to 40 CFR part 194). The EPA's approval process for waste generator sites is described in § 194.8. As part of EPA's decision-making process, the DOE is required to submit to EPA appropriate documentation of quality assurance and waste characterization programs at each DOE waste generator site seeking approval for shipment of TRU radioactive waste to WIPP. In accordance with § 194.8, EPA will place such documentation in the official Air Docket in Washington, DC, and informational dockets in the State of New Mexico for public review and comment.

EPA will perform an inspection of Hanford's technical program for waste characterization in accordance with Condition 3 of the WIPP certification. We will evaluate the adequacy, implementation, and effectiveness of the applicable technical activities related to the Hanford TRU waste characterization program. We will confirm the continued adequacy of waste characterization processes at Hanford for (a) retrievably-stored, contact-handled debris at the Waste Receiving and Processing (WRAP) facility, and (b) homogeneous solids characterized at the Plutonium Finishing Plant (PFP) approved previously by EPA. These include: (1) Segmented Gamma Scanning Assay System at the Plutonium Finishing Plant for characterizing debris and solids; (2) Gamma Energy Assay (GEA) System Units A and B at the Waste Receiving and Processing (WRAP) facility used for characterizing retrievably-stored CH-debris waste; (3) visual examination at WRAP and PFP; and (4) other processes (such as acceptable knowledge, radiography, visual examination, data verification & validation). Also, we will evaluate capabilities of the following new equipment to characterize debris and solids, as applicable: (1) SGSAS at PFP Room 172; (2) seven calorimeters at PFP; (3) two Integrated Passive and Active Neutron (IPAN) systems at WRAP; and (4) visual examination technique at WRAP. The inspection is scheduled to take place the week of June 16, 2003.

EPA has placed DOE documents pertinent to the inspection in the public docket described in **ADDRESSES.** These include: (1) Hanford Site Transuranic Waste Certification Plan, HNF2600, Rev. 10, May 2003 and (2) Hanford Site Transuranic Waste Characterization Quality Assurance Project Plan, HNF 2599, Draft Rev. 9, May 2003. The documents are included in item II–A2–44 in Docket A–98–49. In accordance with 40 CFR 194.8, as amended by the final certification decision, EPA is providing the public 30 days to comment on these documents.

If EPA determines as a result of the inspection that the proposed processes and programs at Hanford adequately control the characterization of transuranic waste, we will notify DOE by letter and place the letter in the official Air Docket in Washington, DC, as well as in the informational docket locations in New Mexico. A letter of approval will allow DOE to ship transuranic waste characterized by the approved processes from Hanford to the WIPP. The EPA will not make a determination of compliance prior to the inspection or before the 30-day comment period has closed. Information on the certification decision is filed in the official EPA Air Docket, Docket No. A–93–02 and is available for review in Washington, DC, and at three EPA WIPP informational docket locations in New Mexico. The dockets in New Mexico

contain only major items from the official Air Docket in Washington, DC, plus those documents added to the official Air Docket since the October 1992 enactment of the WIPP LWA.

Dated: May 30, 2003.

**Robert Brenner,**

*Acting Assistant Administrator for Air and Radiation.*

[FR Doc. 03–14186 Filed 6–3–03; 8:45 am]

**BILLING CODE 6560–50–P**

## FEDERAL COMMUNICATIONS COMMISSION

### 47 CFR Part 73

**[DA 03–1684, MB Docket No. 03–121, RM–10707]**

### Television Broadcast Service; Longview, TX

**AGENCY:** Federal Communications Commission.

**ACTION:** Proposed rule.

**SUMMARY:** The Commission requests comments on a petition filed by Estes Broadcasting, Inc., permittee of channel 54+, proposing the substitution of channel 38 − for channel 54+ at Longview, Texas. TV Channel 38 − can be allotted to Longview, Texas, with a minus offset at reference coordinates 32–35–23 N. and 95–23–27 W.

**DATES:** Comments must be filed on or before July 14, 2003, and reply comments on or before July 29, 2003.

**ADDRESSES:** Federal Communications Commission, 445 12th Street, SW., Room TW–A325, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or its counsel or consultant, as follows: Lee G. Petro, Fletcher, Heald & Hildreth, PLC, 11th Floor, 1300 North 17th Street, Arlington, Virginia 22209–3801 (Counsel for Estes Broadcasting, Inc.).

**FOR FURTHER INFORMATION CONTACT:** Pam Blumenthal, Media Bureau, (202) 418–1600.

**SUPPLEMENTARY INFORMATION:** This is a synopsis of the Commission's Notice of Proposed Rule Making, MB Docket No. 03–121, adopted May 14, 2003, and released May 21, 2003. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, S.W., Room CY–A257, Washington, DC, 20554. This document may also be purchased from the Commission's duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY–B402, Washington, DC, 20554, telephone 202–863–2893, facsimile 202–863–2898, or via-e-mail *qualexint@aol.com.*

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. *See* 47 CFR 1.1204(b) for rules governing permissible *ex parte* contacts.

For information regarding proper filing procedures for comments, *see* 47 CFR 1.415 and 1.420.

**List of Subjects in 47 CFR Part 73**

Television broadcasting.

For the reasons discussed in the preamble, the Federal Communications Commission proposes to amend 47 CFR Part 73 as follows:

## PART 73—RADIO BROADCAST SERVICES

1. The authority citation for part 73 continues to read as follows:

**Authority:** 47 U.S.C. 154, 303, 334 and 336.

**§ 73.606 [Amended]**

2. Section 73.606(b), the Table of Television Allotments under Texas, is amended by removing Channel 54+ and adding Channel 38 − at Longview.

Federal Communications Commission.

**Barbara A. Kreisman,**

*Chief, Video Division, Media Bureau.*

[FR Doc. 03–14007 Filed 6–3–03; 8:45 am]

**BILLING CODE 6712–01–P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

### 50 CFR Part 16

**RIN 1018–AG70**

### Injurious Wildlife Species; Black Carp (*Mylopharyngodon piceus*)

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Proposed rule; reopening of comment period.

**SUMMARY:** The U.S. Fish and Wildlife Service announces the reopening of the public comment period on the proposed rule to add black carp (*Mylopharyngodon piceus*) to the list of injurious fish, mollusks, and crustaceans under the Lacey Act. We are reopening the comment period at this time in order to collect the best and most current scientific and economic data available on the proposed rule. Comments previously submitted need not be resubmitted as they will be incorporated into the public record and will be fully considered in the preparation of the next action.

**DATES:** Comments must be submitted on or before August 4, 2003.

**ADDRESSES:** Comments may be hand-delivered, mailed, or sent by fax to the Chief, Division of Environmental Quality, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Suite 322, Arlington, VA 22203; FAX (703) 358–1800. You may send comments by electronic mail (e-mail) to: *BlackCarp@fws.gov. See* the Public Comments Solicited section below for file format and other information about electronic filing.

**FOR FURTHER INFORMATION CONTACT:** Kari Duncan, Division of Environmental Quality, Branch of Invasive Species, at (703) 358–2464 or *kari_duncan@fws.gov.*

**SUPPLEMENTARY INFORMATION:**

**Background**

The U.S. Fish and Wildlife Service published a proposed rule to add black carp to the list of injurious fish, mollusks, and crustaceans under the Lacey Act on July 30, 2002 (67 FR 49280). This listing would have the effect of prohibiting the importation of any live animal or viable egg of the black carp into the United States and prohibiting the movement of black carp or viable eggs between States without a permit issued by the Director of the Service. The best available information indicates that this action is necessary to protect the interests of human beings, and wildlife and wildlife resources from the purposeful or accidental introduction and subsequent establishment of black carp populations into ecosystems of the United States. As proposed, live black carp or viable eggs could be imported only by permit for scientific, medical, educational, or zoological purposes, or without a permit by Federal agencies solely for their own use; permits would also be required for the interstate transportation of live black carp or viable eggs currently held in the United States for scientific, medical, educational, or zoological purposes. The proposal would prohibit interstate transportation of live black carp or viable eggs currently held in the United States for any other purpose.

The 60-day comment period on the proposed rule to add black carp to the list of injurious wildlife closed on