Proposed Rules

Federal Register
Vol. 62, No. 189
Tuesday, September 30, 1997

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 312, 314, and 601

[Docket No. 97N–0165]

RIN 0910–AB20

Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of a public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss issues related to the agency's proposed rule on regulations requiring manufacturers to assess the safety and effectiveness of new drugs and biological products in pediatric patients. The proposed rule, previously announced in the **Federal Register**, requested written comments and proposed new regulations requiring pediatric studies of certain new drug and biological products. The purpose of the meeting is to provide experts in the field and interested individuals an opportunity to discuss specific issues raised by the proposed rule. The agency is seeking comment and specific data on the proposed rule.

DATES: The public meeting will be held on October 27, 1997, from 9 a.m. to 6 p.m. Please arrive no later than 8:30 a.m. to allow time for security clearance. Written requests for oral presentations should be received by the agency on or before October 14, 1997. Written comments must be submitted on or before November 13, 1997.

ADDRESSES: The public meeting will be held at the Cohen Bldg., auditorium, 330 C St. SW., Washington, DC. Submit written requests for oral presentations to Lisa Barclay, Office of Policy (HF–22), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. To expedite processing, fax written requests for oral presentations to 301–594–6777. To ensure timely handling, the outer envelope or facsimile cover sheet should be clearly marked with: Docket No. 97N–0165, ''Pediatric Labeling Meeting,'' ATTN: Lisa Barclay. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Khyati N. Roberts, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779, FAX 301–594–5493, e-mail robertsk@cder.fda.gov, or

Elaine C. Esber, Center for Biologics Evaluation and Research (HFM–30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–0641, FAX 301–827–0644, e-mail esber@1.cber.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 15, 1997 (62 FR 43900), the agency published a proposed rule for new regulations requiring pediatric studies of certain new drug and biological products. The proposed rule would attempt to partially address a lack of pediatric use information by requiring that manufacturers of a limited class of new drug and biological products provide sufficient data and information to support directions for pediatric use for the claimed indications before, or soon after, approval. Manufacturers of a limited class of already marketed drugs and biologics would also, in compelling circumstances, have to provide such data. The proposed rule is part of a comprehensive effort to increase the number of new drug and biological products with clinically significant use in children that carry adequate labeling for use in that subpopulation.

Because of the importance of ensuring the safety and effectiveness of the medications administered to children and the need to address the absence of pediatric labeling in the most effective manner possible, FDA, in cooperation with the American Academy of Pediatrics, is announcing a public meeting at which recognized experts in the field, members of the pharmaceutical industry, and other interested parties will have an opportunity to discuss certain issues raised by the proposed rule. FDA will consider information presented and discussed at the meeting and written comments submitted to the Dockets Management Branch in the development of the final rule. There is no fee for this public meeting.

II. Scope of Meeting

The purpose of this meeting is to complement the process for gathering written comments and recommendations on certain issues raised by the proposed rule. The meeting will provide recognized experts in the field, members of the pharmaceutical industry, and other interested parties an opportunity to discuss these issues. The agency is specifically seeking comment and data on the following:

(1) What should be considered a ''substantial number'' of pediatric patients?

(2) Whether the rule should be restricted to new chemical entities, including new (never-before-approved) drugs, antibiotics and biological products, or whether it should be applied more broadly (e.g., to applications for chemical variations of approved products, new indications, new dosage forms or routes of administration)?

(3) Whether the proposed grounds for waiving the pediatric study requirement are adequate and whether additional grounds may exist?

(4) What would constitute sufficient data or an adequate pediatric clinical trial? and

(5) How should dose and safety levels for each of the different pediatric age groups or stages of development be established? Relevant to this issue, the agency solicits comment on special problems associated with studies in neonates and young infants.

III. Requests for Oral Presentations

Persons who wish to participate in the meeting must file a written or facsimile request for oral presentation with the Office of Policy (address and fax numbers above). The request for oral presentation should contain the speaker's name, address, telephone and fax numbers, title, business affiliation, if any, topic, a brief summary of the

presentation, and approximate amount of time requested for the presentation.

The agency requests that persons or groups having similar interests consolidate their presentations and present them through a single representative. Because presentations will be limited to 1 day, the agency may not be able to accommodate all requests for oral presentations. FDA will allocate the time available for the meeting among the persons who properly file requests for oral presentations. If time permits at the conclusion of the meeting, FDA may allow participation from both interested persons attending the meeting who did not submit a written request for an oral presentation and those who requested an opportunity to make a presentation, but, due to the time limitations, were not granted the request.

IV. Requests for Comments

Interested persons may, on or before November 13, 1997, submit written comments to the Dockets Management Branch (address above). 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. Special Accommodations

In order to accommodate the need for space or technical support, persons who are planning on using audiovisual equipment during their oral presentations are urged to provide advance notice of their planned attendance to one of the contact persons identified above. If you need special accommodations due to a disability, please contact one of the contact persons listed above at least 7 days in advance.

VI. Transcripts

Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

Dated: September 24, 1997,

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–25937 Filed 9-29-97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[DEA–156P]

RIN #1117–aa43

Listed Chemicals; Proposed Establishment of Thresholds for Iodine and Hydrochloric Gas (Hydrogen Chloride Gas)

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Comprehensive Methamphetamine Control Act of 1996 (MCA) establishes that, effective October 3, 1996, iodine and hydrogen chloride gas are List II chemicals under the Controlled Substances Act (CSA). The inclusion of these chemicals under the CSA requires that each regulated person must keep records and file reports as specified in Title 21 Code Federal Regulations (21 CFR) Part 1310. Since the MCA did not establish thresholds for iodine and hydrogen chloride gas, recordkeeping and reporting requirements became applicable to all domestic transactions of these chemicals. While this notice of proposed rulemaking is proposing a domestic threshold of 0.0 kilograms for hydrogen chloride gas, it proposes to set a domestic threshold of 0.4 kilograms for iodine. This iodine threshold will remove the recordkeeping requirement for many iodine transactions.

This notice of proposed rulemaking also proposes to reinsert the table in 21 CFR 1310.04(f)(2)(iv), listing thresholds for exports, transshipments, and international transactions to designated countries set forth in 1310.08(b). The DEA's final rule regarding implementation of the Domestic Chemical Diversion Control Act of 1993, published on June 22, 1995 [60 FR 32447] inadvertently omitted the table from the section.

DATES: Written comments or objections must be received on or before December 1, 1997.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Frank Sapienza, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–7183.

SUPPLEMENTARY INFORMATION: The MCA was signed into law on October 3, 1996, Section 204 of the MCA amends Section 102(35) of the CSA (21 U.S.C. 802(35)) to include iodine and hydrogen chloride gas as List II chemicals. Section 204(b)(1) and (2) of the MCA also states that ''iodine shall not be subject to the requirements for listed chemicals provided in section 1018 of the Controlled Substances Import and Export Act (21 U.S.C. 971).'' Therefore, the MCA does not impose import/export requirements on iodine. The MCA, however, does not ''limit the authority of the Attorney General to impose the requirements for listed chemicals provided in section 1018 of the Controlled Substances Import and Export Act (21 U.S.C. 971).'' Although the DEA is not imposing import/export restrictions on iodine at this time, the DEA is currently reviewing available data on iodine to determine if such controls are warranted.

Prior to the MCA, hydrogen chloride gas, also known as anhydrous hydrochloric acid, was already a List II chemical under the CSA (21 CFR 1310.02(b)(8)). Pursuant to 21 CFR 1310.08, all domestic and import transactions of hydrogen chloride gas have been exempt from the regulatory controls under the CSA. In addition, all exports, transshipments and international transactions of hydrogen chloride gas have been exempt from the regulatory controls except those to all South American countries and Panama. Exports to all South American countries and Panama above a threshold of 27 kilograms have been regulated transactions (21 CFR 1310.08(b)). The MCA amends the CSA to impose only domestic controls on iodine and domestic and international controls on hydrogen chloride gas.

The majority of the clandestine laboratories seized in the United States manufacture methamphetamine, a Schedule II controlled substance. Since 1990, more than 2,400 methamphetamine laboratories have been seized in the United States by the DEA. The most frequently used synthesis among clandestine laboratory operators today is the ephedrine/pseudoephedrine reduction method which utilizes hydriodic acid. Hydriodic acid is a List I chemical with a domestic threshold of one liter. With the increased controls on hydriodic acid, clandestine laboratory operators have turned to producing their own hydriodic acid or using iodine directly in the synthesis. Clandestine laboratory