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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 381

[Docket No. RM98–15–000]

Annual Update of Filing Fees

August 17, 1998.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Final rule; annual update of Commission filing fees.

SUMMARY: In accordance with § 381.104 of the Commission's regulations, the Commission issues this update of its filing fees. This notice provides the yearly update using data in the Commission's Payroll Utilization Reporting System to calculate the new fees. The purpose of updating is to adjust the fees on the basis of the Commission's costs for Fiscal Year 1997.

EFFECTIVE DATE: September 23, 1998.

FOR FURTHER INFORMATION CONTACT: Kelly Williams, Office of the Executive Director and Chief Financial Officer, Federal Energy Regulatory Commission, 888 First Street, NE, Room 42–65, Washington, DC 20426, 202–219–2896.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in the Public Reference Room at 888 First Street, NE, Room 2A, Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS can be accessed via Internet through FERC's Homepage (http://www.ferc.fed.us) using the CIPS link or the Energy Information Online icon. The full text of this document will be available on CIPS in ASCII and WordPerfect 6.1 format. CIPS is also available through the Commission's electronic bulletin board service at no charge to the user and may be accessed using a personal computer with a modem by dialing 202–208–1397, if dialing locally, or 1–800–856–3920, if dialing long distance. To access CIPS, set your communications software to 19200, 14400, 12000, 9600, 7200, 4800, 2400 or 1200 bps, full duplex, no parity, 8 data bits, and 1 stop bit. User assistance is available at 202–208–2474 or by E-mail to CipsMaster@FERC.fed.us.

This document is also available through the Commission's Records and Information Management System (RIMS), an electronic storage and retrieval system of documents submitted to and issued by the Commission after November 16, 1981. Documents from November 1995 to the present can be viewed and printed. RIMS is available in the Public Reference Room or remotely via Internet through FERC's Homepage using the RIMS link or the Energy Information Online icon. User assistance is available at 202–208–2222, or by E-mail to RimsMaster@FERC.fed.us.

Finally, the complete text on diskette in WordPerfect format may be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in the Public Reference Room at 888 First Street, NE, Washington, DC 20426.

Annual Update of Filing Fees in Part 381

The Federal Energy Regulatory Commission (Commission) is issuing this notice to update filing fees that the Commission assesses for specific services and benefits provided to identifiable beneficiaries. Pursuant to § 381.104 of the Commission's regulations, the Commission is establishing updated fees on the basis of the Commission's Fiscal Year 1997 costs. The adjusted fees announced in this notice are effective September 23, 1998.

The new fee schedule is as follows:

Fees Applicable to the Natural Gas Policy Act:	
1. Petitions for rate approval pursuant to 18 CFR 284.123(b)(2). [18 CFR 381.403]	$7,140
Fees Applicable to General Activities:	
1. Petition for issuance of a declaratory order (except under Part I of the Federal Power Act). [18 CFR 381.302(a)]	14,360
2. Review of a Department of Energy remedial order:.	
Amount in controversy:	
$0–9,999. [18 CFR 381.303(b)]	100
$10,000–29,999. [18 CFR 381.303(b)]	600
$30,000 or more. [18 CFR 381.303(a)]	20,960
3. Review of a Department of Energy denial of adjustment:	
Amount in controversy:	
$0–9,999. [18 CFR 381.304(b)]	100
$10,000–29,999. [18 CFR 381.304(b)]	600
$30,000 or more. [18 CFR 381.304(a)]	10,990
4. Written legal interpretations by the Office of General Counsel. [18 CFR 381.305(a)]	4,120
Fees Applicable to Natural Gas Pipelines:	
1. Pipeline certificate applications pursuant to 18 CFR 284.224. [18 CFR 381.207(b)]	1,000
Fees Applicable to Cogenerators and Small Power Producers:	
1. Certification of qualifying status as a small power production facility. [18 CFR 381.505(a)]	12,340
2. Certification of qualifying status as a cogeneration facility. [18 CFR 381.505(a)]	13,970
3. Applications for exempt wholesale generator status. [18 CFR 381.801]	1,620

List of Subjects in 18 CFR Part 381

Electric power plants, Electric utilities, Natural gas, Reporting and recordkeeping requirements.

Linwood A. Watson, Jr.,

Acting Secretary.

In consideration of the foregoing, the Commission amends Part 381, Chapter I, Title 18, *Code of Federal Regulations*, as set forth below.

PART 381—FEES

1. The authority citation for Part 381 continues to read as follows:

Authority: 15 U.S.C. 717–717w; 16 U.S.C. 791–828c, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352; 49 U.S.C. 60502; 49 App. U.S.C. 1–85.

§ 381.302 [Amended]

2. In § 381.302, paragraph (a) is amended by removing ''$ 13,910'' and inserting ''$ 14,360'' in its place.

§ 381.303 [Amended]

3. In § 381.303, paragraph (a) is amended by removing ''$ 20,300'' and inserting ''$ 20,960'' in its place.

§ 381.304 [Amended]

4. In § 381.304, paragraph (a) is amended by removing ''$ 10,640'' and inserting ''$ 10,990'' in its place.

§ 381.305 [Amended]

5. In § 381.305, paragraph (a) is amended by removing ''$ 3,990'' and inserting ''$ 4,120'' in its place.

§ 381.403 [Amended]

6. Section 381.403 is amended by removing ''$ 6,920'' and inserting ''$ 7,140'' in its place.

§ 381.505 [Amended]

7. In § 381.505, paragraph (a) is amended by removing ''$ 11,960'' and inserting ''$ 12,340'' in its place and by removing ''$ 13,540'' and inserting ''$ 13,970'' in its place.

§ 381.801 [Amended]

8. Section 381.801 is amended by removing ''$ 1,560'' and inserting ''$ 1,620'' in its place.

[FR Doc. 98–22582 Filed 8–21–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 310

[Docket No. 98N–0636]

RIN 0910–AA01

Status of Certain Additional Over-the-Counter Drug Category II and III Active Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule stating that certain ingredients in over-the-counter (OTC) drug products are not generally recognized as safe and effective or are misbranded. FDA is issuing this final rule after considering the reports and recommendations of various OTC drug advisory review panels and public comments on proposed agency regulations, which were issued in the form of a tentative final monograph (proposed rule). Based on the absence of any submissions on these ingredients to the panels, as well as the failure of interested parties to submit new data or information to FDA under the proposed regulations, the agency has determined that the presence of these ingredients in an OTC drug product would result in that drug product not being generally recognized as safe and effective for its intended use or would result in misbranding. This final rule is part of the ongoing review of OTC drug products conducted by FDA.

EFFECTIVE DATE: February 22, 1999.

FOR FURTHER INFORMATION CONTACT: Gerald M. Rachanow, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2307.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of November 7, 1990 (55 FR 46914), FDA published under § 330.10(a)(7)(ii) (21 CFR 330.10(a)(7)(ii)) a final rule on the status of certain OTC drug Category II and III active ingredients. That final rule declared as not generally recognized as safe and effective certain active ingredients that had been proposed as nonmonograph (Category II or Category III) under the agency's OTC drug review. The periods for submission of comments and new data following the publication of a notice of proposed rulemaking (NPRM) had closed and no significant comments or new data had been submitted to upgrade the status of these ingredients. In each instance, a final rule for the class of ingredients involved had not been published to date.

In the **Federal Register** of May 10, 1993 (58 FR 27636), FDA published a final rule establishing that certain additional active ingredients in OTC drug products are not generally recognized as safe and effective or are misbranded. That final rule included active ingredients from a number of OTC drug rulemakings that were not covered by the November 7, 1990, final rule (see Table I of the May 10, 1993, final rule (58 FR 27636 at 27639 to 27641) for a list of OTC drug rulemakings and active ingredients covered by that final rule). The final rule included a number of active ingredients found in OTC internal analgesic and orally administered menstrual drug products. Those ingredients are listed in § 310.545(a)(23) and (a)(24) (21 CFR 310.545(a)(23) and (a)(24)), respectively.

The ingredients listed in these sections do not include ephedrine, ephedrine salts (ephedrine hydrochloride, ephedrine sulfate, racephedrine hydrochloride), atropine, or atropine salts (atropine sulfate). The agency is aware of several combination drug products marketed for OTC internal analgesic or menstrual use that include ephedrine sulfate and atropine sulfate among their ingredients, in addition to aspirin or acetaminophen (Ref. 1). No submissions of data supporting the use of ephedrine or atropine singly or in combination were made to the advisory review panels that reviewed these classes of OTC drug products. No information was provided following publication of the tentative final monographs for OTC orally administered menstrual drug products or internal analgesic, antipyretic, and antirheumatic drug products on November 16, 1988 (53 FR 46194 and 46204, respectively). A final rule has not been published to date for either of these classes of OTC drug products.

FDA is not aware of any information that supports the use of ephedrine or atropine as active ingredients in OTC orally administered menstrual or internal analgesic, antipyretic, and antirheumatic drug products. Accordingly, these active ingredients will not be included in the relevant final monographs because they have not been shown to be generally recognized as safe and effective for their intended use(s). These ingredients should be eliminated from OTC drug products 180 days after the date of publication in the **Federal Register** of this final rule, regardless of whether further testing is undertaken to justify future use.

Publication of a final rule under this proceeding does not preclude a manufacturer's testing an ingredient. New, relevant data can be submitted to the agency at a later date as the subject of a new drug application (NDA) that may provide for prescription or OTC marketing status (see part 314 (21 CFR part 314)). As an alternative, where there are adequate data establishing general recognition of safety and effectiveness, such data may be submitted in an appropriate citizen petition to amend a monograph (see § 10.30 (21 CFR 10.30)).

II. The Agency's Final Conclusions on Certain OTC Drug Category II and III Ingredients

The agency notes that no comments or data have been submitted to the OTC drug review to support any ephedrine or atropine ingredient as being generally recognized as safe and effective for any OTC uses in orally administered menstrual or internal analgesic, antipyretic, and antirheumatic drug products. The agency has determined that these ingredients should be deemed not generally recognized as safe and effective for OTC use before a final monograph for each respective drug category is established. Accordingly, any drug product containing any of these ingredients and labeled for OTC