negotiation of fees. By orchestrating agreements among its members to deal only on collectively-determined terms, and actual or threatened refusals to deal with health plans that would not agree to those terms, San Juan IPA violated Section 5 of the FTC Act.

The Proposed Consent Order

The proposed order is designed to remedy the illegal conduct charged in the complaint and prevent its recurrence. It is similar to recent consent orders that the Commission has issued to settle charges that physician groups engaged in unlawful agreements to raise fees they receive from health plans.

The proposed order's specific provisions are as follows:

Paragraph II.A prohibits San Juan IPA from entering into or facilitating any agreement between or among any physicians: (1) To negotiate with payors on any physician's behalf; (2) to deal, not to deal, or threaten not to deal with payors; (3) on what terms to deal with any payor; or (4) not to deal individually with any payor, or to deal with any payor only through an arrangement involving San Juan IPA.

Other parts of Paragraph II reinforce these general prohibitions. Paragraph II.B prohibits San Juan IPA from facilitating exchanges of information between physicians concerning whether, or on what terms, to contract with a payor. Paragraph II.C bars attempts to engage in any action prohibited by Paragraph II.A or II.B, and Paragraph II.D proscribes inducing anyone to engage in any action prohibited by Paragraphs II.A through II.C.

As in other Commission orders addressing providers' collective bargaining with health care purchasers, certain kinds of agreements are excluded from the general bar on joint negotiations. San Juan IPA would not be precluded from engaging in conduct that is reasonably necessary to form or participate in legitimate joint contracting arrangements among competing physicians in a ''qualified risk-sharing joint arrangement'' or a ''qualified clinically-integrated joint arrangement.'' The arrangement, however, must not facilitate the refusal of, or restrict, physicians in contracting with payors outside of the arrangement.

As defined in the proposed order, a ''qualified risk-sharing joint arrangement'' possesses two key characteristics. First, all physician participants must share substantial financial risk through the arrangement, such that the arrangement creates incentives for the physician participants jointly to control costs and improve quality by managing the provision of services. Second, any agreement concerning reimbursement or other terms or conditions of dealing must be reasonably necessary to obtain significant efficiencies through the joint arrangement.

A ''qualified clinically-integrated joint arrangement,'' on the other hand, need not involve any sharing of financial risk. Instead, as defined in the proposed order, physician participants must participate in active and ongoing programs to evaluate and modify their clinical practice patterns in order to control costs and ensure the quality of services provided, and the arrangement must create a high degree of interdependence and cooperation among physicians. As with qualified risk-sharing arrangements, any agreement concerning price or other terms of dealing must be reasonably necessary to achieve the efficiency goals of the joint arrangement.

Paragraph III, for three years, requires San Juan IPA to notify the Commission before participating in contracting with health plans on behalf of a qualified risk-sharing joint arrangement or a qualified clinically-integrated joint arrangement. Paragraph III also sets out the information necessary to make the notification complete.

Paragraph IV, for three years, requires San Juan IPA to notify the Commission before entering into any arrangement to act as a messenger, or as an agent on behalf of any physicians, with payors regarding contracts. Paragraph IV also sets out the information necessary to make the notification complete.

Paragraph V.A requires San Juan IPA to distribute the complaint and order to all physicians who have participated in San Juan IPA, and to payors that negotiated contracts with San Juan IPA or indicated an interest in contracting with San Juan IPA. Paragraph V.B requires San Juan IPA, at any payor's request and without penalty, or, at the latest, within one year after the order is made final, to terminate its current contracts. Paragraph V.C requires San Juan IPA to distribute payor requests for contract termination to all physicians who participate in San Juan IPA. Paragraph V.D.1.b requires San Juan IPA to distribute the complaint and order to any payors that negotiate contracts with San Juan IPA in the next three years.

Paragraphs VI and VII of the proposed order impose various obligations on San Juan IPA to report or provide access to information to the Commission to facilitate monitoring San Juan IPA's compliance with the order.

The proposed order will expire in 20 years.

By direction of the Commission, Chairman Majoras not participating.

Donald S. Clark,

Secretary.

[FR Doc. 05–10682 Filed 5–27–05; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0178]

Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on reporting and recordkeeping requirements in implementing the Federal Import Milk Act (FIMA).

DATES: Submit written or electronic comments on the collection of information by August 1, 2005.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of

information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Regulations Under the Federal Import Milk Act—21 CFR Part 1210 (OMB Control Number 0910–0212)—Extension

Under the regulations implementing FIMA (21 U.S.C. 141–149), milk or cream may be imported into the United States only by the holder of a valid import milk permit. Before such permit is issued: (1) All cows from which import milk or cream is produced must be physically examined and found healthy; (2) if the milk or cream is imported raw, all such cows must pass a tuberculin test; (3) the dairy farm and each plant in which the milk or cream is processed or handled must be inspected and found to meet certain sanitary requirements; (4) bacterial counts of the milk at the time of importation must not exceed specified limits; and (5) the temperature of the milk or cream at time of importation must not exceed 50° F. In addition, the regulations in part 1210 (21 CFR part 1210) require that dairy farmers and plants maintain pasteurization records (§ 1210.15) and that each container of milk or cream imported into the United States bear a tag with the product type, permit number, and shipper's name and address (§ 1210.22).

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA 1815/Permits granted on certificates	1210.23	8	1	8	0.5	4.0
FDA 1993/Application of permit	1210.20	8	1	8	0.5	4.0
FDA 1994/Tuberculin test	1210.13	1	1	1	0.5	0.5
FDA 1995/Physical examination of cows	1210.12	1	1	1	0.5	0.5
FDA 1996/Sanitary inspection of dairy farms	1210.11	8	200	1,600	1.5	2,400
FDA 1997/Sanitary inspections of plants	1210.14	8	1	8	2.0	16.0
Total						2,425.0

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1210.15	8	1	8	0.05	0.40

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on the number of current permit holders and the number of inquiries that FDA has received regarding requests for applications in the past 3 years. No burden has been estimated for the tagging requirement in § 1210.22 because the information on the tag is either supplied by FDA (permit number) or is disclosed to third parties as a usual and customary part of the shipper's normal business activities (type of product, shipper's name and address). Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information. Under 5 CFR 1320.3(b)(2)), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. Low burden has been estimated for Forms FDA 1994 and 1995 because they are not are not used often.

The Secretary of Health and Human Services has the discretion to allow Form FDA 1815, a duly certified statement signed by an accredited official of a foreign government, to be submitted in lieu of Forms FDA 1994 and 1995. To date, Form FDA 1815 has been submitted in lieu of these forms.

Dated: May 17, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–10703 Filed 5–27–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0174]

Draft Guidance on Expiration Dating of Unit-Dose Repackaged Drugs; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''Expiration Dating of Unit-Dose Repackaged Drugs.'' The draft guidance is a proposed revision of section 480.200 of FDA's Compliance Policy Guide (CPG) (CPG 7132b.11). We are proposing to revise CPG 7132b.11 so that FDA enforcement policy regarding expiration dating of nonsterile unit-dose repackaged drugs under the agency's current good manufacturing practice (CGMP) regulations is substantially comparable to the expiration dating standards for such drugs set forth in the U.S. Pharmacopeia (USP).

DATES: Submit written or electronic comments on the draft guidance by August 29, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.* See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Barry Rothman, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–9026.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a draft guidance on ''Expiration Dating of Unit-Dose Repackaged Drugs.'' The document provides guidance on FDA's enforcement policy regarding expiration dating of repackaged nonsterile solid and liquid unit-dose drugs under § 211.137 (21 CFR 211.137). Specifically, the draft guidance states certain circumstances under which we intend to exercise enforcement discretion and do not intend to take action against repackagers for failure to conduct stability studies to support expiration dates for drug products in accordance with FDA regulations.

The draft guidance is a proposed revision of section 480.200 of the CPG (CPG 7132b.11), which we issued in February 1984 and revised in March 1995. We originally issued CPG 7132b.11 because unit-dose packaging systems had become widespread in health care, and questions had arisen as to whether drugs that were repackaged into unit-dose containers needed expiration dates based on stability data on the drugs in the unit-dose containers.

The CGMP regulations require that each drug product bear an expiration date derived from tests conducted on samples stored in the immediate container closure system in which the drug is marketed (see § 211.137(a), § 211.166(a)(4) (21 CFR 211.166(a)(4))). This expiration dating ensures the drugs' safety and efficacy over their intended shelf life. CPG 7132b.11 notes that the USP contains standards on beyond-use dating of nonsterile solid and liquid unit-dose drug products.

Since its adoption in 1984, the CPG has stated that, in light of the USP standards and under certain conditions, the agency does not deem it necessary that stability studies be conducted on drugs that are repackaged into unit-dose containers. Therefore, the CPG has stated that we do not intend to initiate enforcement action against any unit-dose repackaging firm for failure to have stability studies supporting expiration dates, provided certain conditions are met, including that the expiration date does not exceed 6 months. At the time the CPG was adopted, this recommendation was substantially comparable to the USP standards on expiration dating of nonsterile unit-dose repackaged drug products.

In 2000, the USP revised its standards on the beyond-use dating of nonsterile solid and liquid dosage forms that are packaged in single-unit and unit-dose containers. The USP now states that, for such products, the beyond-use date must be 1 year from the date the drug is packaged into the single-unit or unit-dose container or the expiration date on the manufacturer's container, whichever is earlier, unless stability data or the manufacturer's labeling indicates otherwise (USP 27, General Notices and Requirements, at 11).

We have considered the USP revision to its beyond-use standard and believe that similar conditions are appropriate for CPG 7132b.11 for expiration dating. We believe that under certain specified conditions, it may be appropriate to assign up to a one-year expiration dating period to solid and liquid oral dosage form drug products repackaged into unit-dose containers, without conducting new stability studies on the repackaged drug products. Therefore, we are proposing to revise CPG 7132b.11 to clarify the agency's exercise of enforcement discretion concerning expiration dating of nonsterile solid and liquid oral dosage form drug products that are repackaged into unit-dose containers.

Under draft revised CPG 7132b.11, the expiration date for a nonsterile repackaged unit-dose drug would not exceed the following: (1) One year from the date of repackaging, or (2) the expiration date on the container of the original manufacturer's product, whichever is earlier, unless stability data or the original manufacturer's product labeling indicated otherwise, and provided certain other recommendations specified in CPG 7132b.11 were met. These other conditions include, but are not limited to, standards for containers, repackaging operations, and the repackaging environment.

Additionally, because CPG 7132b.11 serves as Attachment B to section 430.100 of the CPG (CPG 7132b.10, ''Unit Dose Labeling for Solid and Liquid Oral Dosage Forms''), the proposed revision of CPG 7132b.11 will serve as Attachment B to CPG 7132b.10 when CPG 7132b.11 is finalized.

We invite comments on the draft guidance. Additionally, we intend to conduct further study of the appropriateness of the proposed revision of CPG 7132b.11 regarding expiration dating on the unit-dose containers of nonsterile repackaged solid and liquid oral dosage form drug