FEDERAL RESERVE SYSTEM

Board of Governors

Government in the Sunshine; Meeting Notice

AGENCY HOLDING THE MEETING: Board of Governors of the Federal Reserve System.

TIME AND DATE: 11 a.m., Tuesday, January 16, 2001.

PLACE: Marriner S. Eccles Federal Reserve Board Building, 20th and C Streets, NW., Washington, DC 20551

STATUS: Closed.

MATTERS TO BE CONSIDERED:

1. Personnel actions (appointments, promotions, assignments, reassignments, and salary actions) involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

CONTACT PERSON FOR MORE INFORMATION: Lynn S. Fox, Assistant to the Board; 202–452–3204.

SUPPLEMENTARY INFORMATION: You may call 202–452–3206 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Dated: January 5, 2001.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 01–782 Filed 1–5–01; 4:59 pm]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

Office of Communications; Cancellation of a Standard Form

AGENCY: General Services Administration.

ACTION: Notice.

SUMMARY: The following Standard Form is cancelled because of low usage: SF 81A, Space Requirements Worksheet.

DATES: Effective upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581.

Dated: December 21, 2000.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer.

[FR Doc. 01–665 Filed 1–9–01; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Order/Notice to withhold income for child support.

OMB No.: 0970–0154.

Description: Public Law 104–193, The Personal Responsibility and Work Opportunity Reconciliation Act (PRWORA) of 1996, section 324—Use of Forms in Interstate Enforcement requires the Federal Office of Child Support Enforcement (CSE) agencies and courts/tribunals must use to collect child support payments from an obligor's employer.

The form, which promotes standardization expired 12/31/2000 and we are taking this opportunity to make revisions to reflect the Uniform Interstate Family Support Act (UIFSA) and the mandate the use for IV–D and non IV–D direct withholding cases. The 2-page form provides a detailed legal description of the established order, support amounts, and remittance information an employer needs to withhold payments from obligor who owes child support.

Respondents: State, Local, and Tribal Governments Annual Burden Estimates.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Order/Notice	54	1	.1666	9
Estimated Total Annual Burden Hours	.....	.....	.....	9

Additional Information: Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget
Paperwork Reduction Project
725 17th Street, NW
Washington, DC 20503
Attn: Desk Office for ACF

Dated: January 4, 2001.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 01–634 Filed 1–9–01; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0861]

Determination of Regulatory Review Period for Purposes of Patent Extension; Synvisc Hylan G–F 20 (4,713,448)®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Synvisc Hylan G–F 20 (4,713,448)® and is publishing this notice of that determination as required by law. FDA has made the determination because of

the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device Synvisc Hylan G–F 20 (4,713,448)®. Synvisc Hylan G–F 20 (4,713,448)® is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative nonpharmacologic therapy and to simple analgesics (e.g., acetaminophen). Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Synvisc Hylan G–F 20 (4,713,448)® (U.S. Patent No. 4,713,448) from Biomatrix, Inc., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated December 11, 1998, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of Synvisc Hylan G–F 20 (4,713,448)® represented the first permitted commercial marketing or use of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Synvisc Hylan G–F 20 (4,713,448)® is 2,949 days. Of this time, 1,783 days occurred during the testing phase of the regulatory review period, while 1,166 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun:* July 14, 1989. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective July 14, 1989.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e):* May 31, 1994. FDA has verified the applicant's claim that the premarket approval application (PMA) for Synvisc Hylan G–F 20 (4,713,448)® (PMA P940015) was initially submitted May 31, 1994.

3. *The date the application was approved:* August 8, 1997. FDA has verified the applicant's claim that PMA P940015 was approved on August 8, 1997.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 396 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may submit to the Dockets Management Branch (address above) written comments and ask for a redetermination by March 12, 2001. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 9, 2001. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30. Comments and petitions should be submitted to the Dockets Management Branch. Three copies of any information 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. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 20, 2000.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 01–681 Filed 1–9–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98E–0613]

Determination of Regulatory Review Period for Purposes of Patent Extension; Synvisc Hylan G–F 20 (5,143,724)®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Synvisc Hylan G–F 20 (5,143,724)® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit written comments and petitions to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Regulatory Policy Staff (HFD–007), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5645.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public