DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

Statement of Organization, Functions, and Delegations of Authority

This notice amends Part F, Section F.70 (Order of Succession) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (HHS), Centers for Medicare & Medicaid Service (CMS), 75 FR 71714, dated November 24, 2010, which is rescinded and replaced by the following:

Orders of Succession

1. During any period when the Administrator, Centers for Medicare & Medicaid Services (CMS) has died, resigned, or otherwise becomes unable to perform the functions and duties in the Office of the Administrator, CMS, the following officers, in the Order of Succession listed below, shall act for and perform the functions and duties of the Office of the Administrator, CMS, until such time as: the Administrator, CMS, again becomes available; a permanent successor is appointed by the President and confirmed by Congress; or the temporary successor is otherwise relieved:

a. Principal Deputy Administrator.

b. Deputy Administrator and Director, Center for Medicare.

c. Deputy Administrator and Director, Center for Medicaid and CHIP Services.

d. Chief of Staff.

e. Chief Operating Officer.

2. During any period when there is no eligible officer available or capable of performing responsibilities in the Office of the Administrator, CMS, pursuant to the officers listed in 1.a. through 1.e. above, the following positions in CMS, in the Order of Succession listed below, shall act and perform the functions and duties inherent in the Emergency Operations Executive (EOE) in the event of an emergency situation:

a. Consortium Administrator, Consortium for Quality Improvement and Survey & Certification Operations.

b. Consortium Administrator, Consortium for Financial Management and Fee For Service Operations.

c. Consortium Administrator, Consortium for Medicaid and Children's Health Operations.

d. Consortium Administrator, Consortium for Medicare Health Plans Operations.

The authority to act as the Administrator, CMS, must be exercised in accordance with the provisions of the Federal Vacancies Reform Act of 1998 (''the Vacancies Act''), 5 U.S.C. Section 3345 et seq. The ''Acting'' title is applicable and reserved only in instances in which the Administrator, CMS, position is vacant. In accordance with the Vacancies Act, the Principal Deputy Administrator is herein designated as the first assistant for CMS.

During a planned absence, the Administrator, CMS, may designate an individual to serve as ''operationally in charge.'' If an individual is serving in an ''operationally in charge'' capacity, he or she is not eligible for any delegated authority under these Orders of Succession unless he or she was designated as a delegatee by the Administrator, CMS.

The two Orders of Succession listed in this notice are limited to the duties and responsibilities of only the officers and positions. Number 1 can only be exercised in order to accomplish the goals of maintaining the agency's essential functions. Number 2 can only be exercised to restore the agency's normal business functions under the CMS Continuity of Operations Plan.

The EOE is responsible for notifying the Secretary, HHS and any available CMS leadership that the EOE has assumed responsibility.

I, or my successor retain the authority to change, amend, or re-delegate this notice.

The two Orders of Succession listed in this notice remain in effect and will be revised accordingly as positions or nomenclature change in CMS.

This notice only applies to periods when the Administrator, CMS, or his or her successor are not available to perform the duties and responsibilities contained in the two Orders of Succession.

This notice is effective upon date of signature.

Dated: March 27, 2014.

Marilyn Tavenner,

Administrator.

[FR Doc. 2014–07241 Filed 3–31–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Voluntary Establishment of Paternity

OMB No.: 0970–0175

Description: Section 466(a)(5)(C) of the Social Security Act requires States to pass laws ensuring a simple civil process for voluntarily acknowledging paternity under which the State must provide that the mother and putative father must be given notice, orally and in writing, of the benefits and legal responsibilities and consequences of acknowledging paternity. The information is to be used by hospitals, birth record agencies, and other entities participating in the voluntary paternity establishment program that collect information from the parents of children that are born out of wedlock.

Respondents: The parents of children that are born out of wedlock.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
None	1,686,980	1	0.17	286,787

Estimated Total Annual Burden Hours: 286,787.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0329]

Guidance for Industry on Fees for Human Drug Compounding Outsourcing Facilities Under the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' The guidance is intended for entities that compound human drugs and elect to register as outsourcing facilities (outsourcing facility) under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), as added by the Drug Quality and Security Act (DQSA). Entities that elect to register as outsourcing facilities must pay certain fees to be considered outsourcing facilities. This guidance describes the annual establishment fee, the reinspection fee, annual adjustments to fees required by law, how to submit payment, the effect of failure to pay fees, and how to qualify as a small business to obtain a reduction of the annual establishment fee.

DATES: Submit either electronic or written comments on FDA guidances at any time. Submit either electronic or written comments concerning the collection of information proposed in the draft guidance by June 2, 2014.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of User Fee Management and Budget Formulation, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Rm. 2163, Silver Spring, MD 20903. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: M. Jonathan Gil, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Silver Spring, MD 20903, 301–796–7900.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act.'' On November 27, 2013, President Obama signed the DQSA (Pub. L. 113–54) into law. The DQSA added a new section 503B to the FD&C Act that created a category of entities called *outsourcing facilities.* Outsourcing facilities, as defined in section 503B(d)(4) of the FD&C Act, are facilities that meet certain conditions described in section 503B(a), including, registering with FDA as an outsourcing facility and paying associated fees. If the conditions outlined in section 503B(a) of the FD&C Act are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from two sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (2) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs).

This guidance describes in detail the fee types and amounts an entity must pay to satisfy the fee requirements of sections 503B(a)(9) and 744K of the FD&C Act to be deemed an outsourcing facility and maintain its status as an outsourcing facility, the adjustments to the fees required by law, how to qualify as a small business to obtain a reduction of the annual establishment fee, how and when to submit payment to FDA, the effect of failure to pay fees, and fee-related dispute resolution.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection are given under this section with an estimate of the reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

We invite 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.

Title: Guidance for Industry on Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act; Availability.

Description: The draft guidance pertains to entities that compound human drugs and elect to register as outsourcing facilities. These outsourcing facilities must pay certain fees to FDA. The draft guidance describes the fee