Management, and DHHS policies and instructions.

This delegation became effective upon date of signature. I hereby affirm and ratify any actions taken that involve the exercise of the authorities delegated herein prior to the effective date of this delegation.

Dated: November 14, 2012.

Thomas R. Frieden,

Director, Centers for Disease Control and Prevention.

[FR Doc. 2012–28733 Filed 11–27–12; 8:45 am]

BILLING CODE 4160–18–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Support Enforcement Program Expenditure Report (Form OCSE–396A) and the Child Support Enforcement Program Collection Report (Form OCSE–34A).

OMB No.: 0970–0181.

Description: State and Tribal agencies administering the Child Support Enforcement Program under Title IV–D of the Social Security Act are required to provide information each fiscal quarter to the Office of Child Support Enforcement (OCSE) concerning administrative expenditures and the receipt and disposition of child support payments from non-custodial parents. State title IV–D agencies report quarterly expenditures and collections using Forms OCSE–396A and OCSE–34A, respectively. Tribal title IV–D agencies report quarterly expenditures using Form SF–269, as prescribed in program regulations, and formerly reported quarterly collections using only a modified version of Form OCSE–34A. The information collected on these reporting forms is used to compute quarterly grant awards to States and Tribes, the annual incentive payments to States and provides valuable information on program finances. This information is also included in a published annual statistical and financial report, available to the general public.

In response to an earlier **Federal Register** Notice (75 FR 10805, March 9, 2010), this agency received insufficient comments to support any substantial changes to these forms at this time. However, we continue to discuss improvements to these reporting forms with State and Tribal grantees and anticipate some minor revisions will be proposed in the near future. These revisions will be limited to any changes that may be necessitated by the expiration of program requirements under the ''American Recovery and Reinvestment Act of 2009'' (ARRA) and changes to reporting instructions that will allow Tribal grantees to, at least, use the same quarterly collection report submitted by State grantees.

Respondents: State agencies (including the District of Columbia, Puerto Rico, Guam and the Virgin Islands) administering the Child Support Enforcement Program.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
OCSE–396A	54	4	6	1,296
OCSE–34A	54	4	14	3,024

Estimated Total Annual Burden Hours: 4,320.

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.

[FR Doc. 2012–28795 Filed 11–27–12; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0386]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On August 9, 2012, the Agency submitted a proposed collection of information entitled ''Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments and Listing of Ingredients in Tobacco Products'' to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0650. The approval expires on October 31, 2015. A copy of the supporting statement for this information collection is available on the Internet at *http://www.reginfo.gov/public/do/PRAMain.*

Dated: November 21, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–28774 Filed 11–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1134

Sodium Nitrite Injection and Sodium Thiosulfate Injection Drug Products Labeled for the Treatment of Cyanide Poisoning; Enforcement Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to take enforcement action against unapproved injectable drug products containing sodium nitrite labeled for the treatment of cyanide poisoning and unapproved injectable drug products containing sodium thiosulfate labeled for the treatment of cyanide poisoning, and persons who manufacture or cause the manufacture or distribution of such products in interstate commerce. Cyanide antidotes carry serious risks and some unapproved drug products may lack Boxed Warnings and other warnings required in the labeling of approved cyanide antidotes. These unapproved drug products compete with approved products, and thus pose a direct challenge to the drug approval system. Injectable drug products containing sodium nitrite or sodium thiosulfate that are labeled for the treatment of cyanide poisoning are new drugs that require approved new drug applications (NDAs) or abbreviated new drug applications (ANDAs) in order to be legally marketed.

DATES: This notice is effective November 28, 2012. For information about enforcement dates, see **SUPPLEMENTARY INFORMATION**, section IV.

ADDRESSES: All communications in response to this notice should be identified with Docket No. FDA–2012–N–1134 and directed to the appropriate office listed in this document.

Applications under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(b)): Division of Anesthesia, Analgesia, and Addiction Products, Office of New Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993–0002.

Applications under section 505(j) of the FD&C Act (21 U.S.C. 355(j)): Office of Generic Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.

All other communications: Lori Cantin, Office of Unapproved Drugs and Labeling Compliance, Division of Prescription Drugs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5239, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: Lori Cantin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5239, Silver Spring, MD 20993–0002, 301–796–1212, email: *lori.cantin@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Cyanide is highly toxic in humans and can be fatal if not immediately treated with an effective antidote. On January 14, 2011, FDA approved NDA 201444 for Nithiodote, a co-packaged Sodium Nitrite Injection and Sodium Thiosulfate Injection drug product, labeled for treatment of acute cyanide poisoning that is judged to be life-threatening. On February 14, 2012, FDA approved NDA 203922 for Sodium Nitrite Injection for sequential use with sodium thiosulfate for treatment of acute cyanide poisoning that is judged to be life-threatening, and NDA 203923 for Sodium Thiosulfate Injection for sequential use with sodium nitrite for treatment of acute cyanide poisoning that is judged to be life-threatening. Sodium thiosulfate and sodium nitrite pose the risk of hypotension (low blood pressure), and sodium nitrite also poses the risk of methemoglobinemia, a disorder characterized by the presence of a higher than normal level of methemoglobin in the blood. Methemoglobin is an oxidized form of hemoglobin that has a decreased affinity for oxygen, resulting in a reduced ability to release oxygen to body tissue. Methemoglobinemia can lead to neurological and cardiac symptoms due to lack of adequate oxygen in body tissues. The approved Sodium Nitrite Injection and Nithiodote carry Boxed Warnings for these serious adverse reactions.

FDA is aware of several unapproved drug products containing sodium nitrite or sodium thiosulfate labeled to treat cyanide poisoning. These unapproved drug products containing sodium nitrite or sodium thiosulfate are sold individually, as well as in cyanide antidote kits. Unapproved cyanide antidote kits may also contain other unapproved drugs (e.g., amyl nitrite) or medical products (e.g., syringes) that are intended for potential use with sodium nitrite and sodium thiosulfate. This notice is issued under sections 502 (21 U.S.C. 352) and 505 of the FD&C Act and applies to unapproved injectable drug products containing sodium nitrite or sodium thiosulfate labeled to treat cyanide poisoning that are currently being manufactured or distributed.

II. Safety Concerns With Unapproved New Drugs

Because marketed unapproved new drug products have not been through FDA's approval process, there are safety risks associated with them. Some unapproved drug product labeling omits safety warnings, such as the Boxed Warnings required on Sodium Nitrite Injection and Nithiodote, which are important for safe use of the drug products. Without these warnings, the unapproved drug products may be used in inappropriate circumstances or without appropriate monitoring, posing an increased risk to public health. Patients being treated for cyanide poisoning require close monitoring and may require repeat doses of antidote, supplemental oxygen, and ventilatory support. Cyanide antidotes containing sodium nitrite or amyl nitrite may induce methemoglobinemia, which may require additional treatment.