Description: This is a new proposed data collection from the Office of Child Care (OCC) for the Onsite Monitoring System.

Section 658I of the Child Care and Development Block Grant Act and Subpart J of 45 CFR, part 98 of the Child Care and Development Fund requires the monitoring of programs funded under the CCDF for compliance with:

(1) The Act;

(2) CCDF Regulations; and

(3) The State/Territory CCDF approved Plan.

The proposed data collection will be used by the Office of Child Care (OCC) to monitor State CCDF Lead Agencies to determine and validate compliance with CCDF regulations and the approved State Plan. The data collection is designed to provide States with the flexibility to propose an approach that is feasible and sufficient to demonstrate compliance based on State circumstances and processes. State Lead Agencies will participate in onsite monitoring based on a 3-year cohort; submitting data once every three years. OCC will begin monitoring for compliance in FY 2019.

The data collection for the first 3-years will focus on 11 topical areas: (1) Disaster Preparedness, Response and Recovery; (2) Consumer Education: Dissemination of Information to Parents, Providers, and General Public (Monitoring Reports and Annual Aggregate Data); (3) Twelve-Month Eligibility; (4) Child: Staff Ratios and Group Sizes; (5) Health and Safety Requirements for Providers (11 Health and Safety Topics); (6) Pre-Service/Orientation and Ongoing Training Requirements for Providers; (7) Inspections for CCDF Licensed Providers; (8) Inspections for License-Exempt CCDF Providers; (9) Ratios for Licensing Inspectors; (10) Child Abuse and Neglect Reporting; and (11) Program Integrity.

In developing the Onsite Monitoring System, OCC convened a workgroup of states to provide feedback and input on the design of the Onsite Monitoring System. As part of the workgroup discussions, states emphasized the need for individualized monitoring because of the complexity of each state's CCDF structure and variance in implementation strategies. As a response, OCC developed the Compliance Demonstration Packet that offers states the opportunity to propose their approach to demonstrating compliance based on how their CCDF program is administered. OCC also consulted other federal programs and monitoring experts on the Onsite Monitoring System's development and incorporated their feedback regarding the efficiency and efficacy of the proposed process.

During the development of the Onsite Monitoring System, OCC conducted pilots in a number of States. Feedback received from pilot States and the pilot results were used to enhance the monitoring process and data collection method. Burden estimates below are based on an analysis of data collected through all of the pilot visits while accounting for variance in state documentation.

Respondents: State grantees and the District of Columbia.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Compliance Demonstration Chart	17	1	16	272
Document Submission Chart	17	1	80	1,360

Estimated Total Annual Burden Hours: 1,632 hours.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. chap 35), 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, 330 C Street SW, Washington, DC 20201. 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. 2018–23536 Filed 10–26–18; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3647]

Endo Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 10 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 10 new drug applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of November 28, 2018.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing.

Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 009165	Delatestryl (testosterone enanthate) Injection, 200 milligrams (mg)/milliliter (mL).	Endo Pharmaceuticals, Inc., 1400 Atwater Dr., Malvern, PA 19355.
NDA 010417	Xylocaine (lidocaine hydrochloride (HCl)) 4% Topical Solution/Sterile Injection.	Fresenius Kabi, USA, LLC, Three Corporate Dr., Lake Zurich, IL 60047.
NDA 016297	Xylocaine (1.5% lidocaine HCl with dextrose 7.5%) Spinal Injection, 2 mL ampules.	Do.
NDA 016724	Norinyl 1+80 (mestranol and norethindrone) 21-Day Tablets, 0.08 mg/1 mg.	GD Searle LLC, a subsidiary of Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 016725	Norinyl 1+80 (mestranol and norethindrone) 28-Day Tablets, 0.08 mg/1 mg.	Do.
NDA 019217	Sodium Chloride 0.9% Injection USP in Plastic Container, 9 mg/mL.	ICU Medical, Inc., 600 N. Field Dr., Lake Forest, IL 60045.
NDA 019222	Dextrose 5% Injection USP in Plastic Container, 50 mg/mL	Do.
NDA 203098	Testosterone Gel, 2.5 mg/1.25 grams (g), 25 mg/2.5 g, 50 mg/5 g.	Perrigo Co., U.S. Agent for Perrigo Israel Pharmaceuticals Ltd., 3490 Quebec Ave. North, Minneapolis, MN 55427.
NDA 204031	Xartemis XR (oxycodone HCl and acetaminophen) Extended-Release Tablets, 7.5 mg/325 mg.	Mallinckrodt Inc., 675 McDonnell Blvd., Hazelwood, MO 63042.
NDA 205777	Targiniq ER (naloxone HCl and oxycodone HCl) Extended-Release Tablets, 5 mg/10 mg, 10 mg/20 mg, and 20 mg/40 mg.	Purdue Pharma, LP, One Stamford Forum, Stamford, CT 06901–3431.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 28, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on November 28, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: October 23, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–23528 Filed 10–26–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0821]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigation of Consumer Perceptions of Expressed Modified Risk Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 28, 2018.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title ''Investigation of Consumer Perceptions of Expressed Modified Risk Claims.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Investigation of Consumer Perceptions of Expressed Modified Risk Claims

OMB Control Number 0910—NEW

I. Background

FDA's Center for Tobacco Products proposes to conduct a study to develop generalizable scientific knowledge to help inform its implementation of section 911 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 387k), wherein FDA will be evaluating information submitted to the Agency about how consumers understand and perceive modified risk tobacco products (MRTPs). Section 911 of the FD&C Act authorizes FDA to grant orders to persons to allow the marketing of MRTPs. The term ''modified risk tobacco product'' means any tobacco product that is sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products. FDA can issue a risk modification order under section 911(g)(1) of the FD&C Act authorizing the marketing of an MRTP only if the Agency determines that the product, as it is used by consumers, will significantly reduce harm and the risk of tobacco-related disease to individual tobacco users and benefit the health of the population as a whole, taking into account both users of tobacco products and persons who do not currently use tobacco products (section 911(g)(1) of the FD&C Act). Alternatively, with respect to tobacco products that may not be commercially marketed under section 911(g)(1) of the FD&C Act, FDA may issue an exposure modification order under section 911(g)(2) of the FD&C Act authorizing the marketing of an MRTP if the Agency determines that the standard in section 911(g)(2) of the FD&C Act is met, including, among other requirements, that: Any aspect of the label, labeling, or advertising that would cause the product to be an MRTP