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Dated: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–08332 Filed 4–11–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–1101]

EMD Serono; Withdrawal of Approval of a New Drug Application for LUVERIS

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is withdrawing approval of a new drug application (NDA) for LUVERIS (lutropin alpha for injection) held by EMD Serono, One Technology Place, Rockland, MA 02370. EMD Serono has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.

DATES: Effective April 12, 2016.

FOR FURTHER INFORMATION CONTACT: Emily Helms Williams, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6280, Silver Spring, MD 20993–0002, 301–796–3381.

SUPPLEMENTARY INFORMATION: FDA approved LUVERIS (lutropin alpha for injection) on October 8, 2004, under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. LUVERIS is indicated for concomitant administration with GONAL–F (follitropin alfa for injection) for stimulation of follicular development in infertile hypogonadotropic hypogonadal women with profound luteinizing hormone deficiency. In a letter dated April 30, 2012, EMD Serono requested that FDA withdraw approval of NDA 021322 for LUVERIS under § 314.150(c). In that letter, EMD Serono noted that, as had been previously discussed with the Agency, it was not feasible to complete a trial that the company had agreed to at the time of approval under subpart H. By letter dated December 8, 2014, FDA notified EMD Serono that, when studies that are required as a condition of approval under the Agency's accelerated approval regulations are not completed, the approval of an application is withdrawn according to the procedures set forth in §§ 314.530 and 314.150(d) rather than under § 314.150(c). FDA requested that EMD Serono submit a new withdrawal request under § 314.150(d).

Following additional correspondence, by letter dated July 23, 2015, EMD Serono requested that FDA withdraw approval of NDA 021322 for LUVERIS under § 314.150(d) because a postmarketing study that was required as a condition of approval under subpart H was not completed. Because that study was required to verify and describe the clinical benefit of the drug product, the clinical benefit of LUVERIS has not been confirmed, and it has not been established to be safe and effective. In its July 23, 2015, letter, EMD Serono waived any opportunity for a hearing otherwise provided under §§ 314.150 and 314.530. FDA responded by letter dated September 2, 2015, acknowledging EMD Serono's request that FDA withdraw approval of LUVERIS under § 314.150(d). FDA also acknowledged that EMD Serono waived its opportunity for a hearing.

Therefore, under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) and § 314.150(d), and under authority delegated by the Commissioner to the Director, Center for Drug Evaluation and Research, approval of NDA 021322, and all amendments and supplements thereto, is withdrawn (see DATES). Distribution of this product in interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the FD&C Act (21 U.S.C. 355(a) and 331(d)).

Dated: April 6, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0560]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 May 12, 2016.

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 0910–0582. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable—OMB Control Number 0910–0582—Extension

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and compliant with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product