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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]

**BILLING CODE 4164–01–P**

## 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 EMD Serono has voluntarily requested that approval of this application be withdrawn, thereby waiving its opportunity for a hearing.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of approval under the Agency's accelerated approval regulations are not completed, the approval of an application is withdrawn according to the procedures set forth in §§ 314.530 and 314.150(d) rather than under § 314.150(c).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.*

[FR Doc. 2016–08336 Filed 4–11–16; 8:45 am]

**BILLING CODE 4164–01–P**

## 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

development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812, Investigational Device Exemptions, under 21 CFR 812.2(c)(3), but FDA's regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1, 21 CFR 56.101, 21 U.S.C. 360j(g)(3)(A), and 21 U.S.C. 360j(g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed consent for research involving leftover or unidentifiable specimens.

In a level 1 guidance document, entitled ''Guidance on Informed Consent for In Vitro Diagnostic Device Studies Using Leftover Human Specimens that are Not Individually Identifiable,'' issued under the Good Guidances Practices regulation, 21 CFR 10.115, FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for clinical investigators, sponsors, and IRBs.

The recommendations of the guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one annual record, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,800 hours ($700 \times 4 = 2{,}800$).

In the **Federal Register** of October 23, 2015 (80 FR 64422), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| The FD&C Act section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeping | Total hours |
|---|---|---|---|---|---|
| 520(g) | 700 | 1 | 700 | 4 | 2,800 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: April 6, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2016–08329 Filed 4–11–16; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2016–N–0832]**

### Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Opportunity for Hearing

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of opportunity for hearing.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Veterinary Medicine (CVM), is proposing to withdraw approval of all new animal drug applications (NADAs) providing for use of carbadox in medicated swine feed. This action is based on CVM's determination that the use of carbadox under the approved conditions of use results in residues of carcinogenic concern in the edible tissues of the treated swine.

**DATES:** Phibro Animal Health Corp. may submit a request for a hearing by May 12, 2016. Submit all data and analysis upon which the request for a hearing relies by July 11, 2016.

**ADDRESSES:** The request for a hearing may be submitted by Phibro Animal Health Corp. by either of the following methods:

*Electronic Submission*

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments to submit your request for hearing. Your request for a hearing submitted electronically, including any attachments to the request for hearing, to *http://www.regulations.gov* will be posted to the docket unchanged.

*Written/Paper Submission*

- *Mail/Hand delivery/Courier (for written/paper request for a hearing):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Because your request for a hearing will be made public, you are solely responsible for ensuring that your request does not include any confidential information that you may not wish to be publicly posted, such as confidential business information, *e.g.,* a manufacturing process. The request for a hearing must include the Docket No. FDA–2016–N–0832 for ''Phibro Animal Health Corp.; Carbadox in Medicated Swine Feed; Opportunity for Hearing.'' The request for a hearing will be placed in the docket and publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Phibro Animal Health Corp. may submit all data and analysis upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- Confidential Submissions—To submit any data and analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analysis. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of any decisions on this matter. The second copy, which will have the claimed confidential