Annually, FDA projects one survey study. FDA is requesting this data collection burden so as not to restrict the Agency's ability to gather information on public sentiment for its proposals in its regulatory and communications programs.

Dated: October 14, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–27019 Filed 10–18–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0510]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Prohibited From Use in Animal Food or Feed

**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 November 18, 2011.

**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 e-mailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0627. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@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.

**Substances Prohibited From Use in Animal Food or Feed—21 CFR Part 589 (OMB Control Number 0910–0627)—(Extension)**

The final rule on bovine spongiform encephalopathy (BSE) (73 FR 22720, April 25, 2008) prohibits the use of certain cattle origin materials in the food or feed of all animals to help prevent the spread of BSE in U.S. cattle. BSE is a progressive and fatal neurological disorder of cattle that results from an unconventional transmissible agent. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSEs). All TSEs affect the central nervous system of infected animals. These measures will further strengthen existing safeguards against BSE.

In the **Federal Register** of July 28, 2011 (76 FR 45259), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

*Description of Recordkeeping for Respondents:* Rendering facilities, medicated feed manufacturers, livestock feeders.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| 21 CFR Section | Number of recordkeepers | Number of records per recordkeeper | Total annual records | Average burden per recordkeeper | Total hours | Total operating & maintenance costs |
|---|---|---|---|---|---|---|
| 589.2001 (c)(2)(vi) and (c)(3)(i) | 175 | 1 | 175 | 20 | 3,500 | $59,500 |
| 589.2001 (c)(2)(ii) | 50 | 1 | 50 | 20 | 1,000 | 17,000 |
| 589.2001 (c)(3)(i)(A) | 175 | 1 | 175 | 26 | 4,550 | 80,580 |
| Total | | | | | 9,050 | 157,080 |

[1] There are no capital costs associated with this collection of information.

The number of recordkeepers times the number of records per recordkeeper equals total annual records. Total annual records times average burden per recordkeeper equals total hours.

*Description of Respondents for Reporting:* The final rule on BSE (73 FR 22720) included a provision that exempts cattle materials prohibited in animal feed (CMPAF) from designated countries from the prohibition on its use in animal feed (21 CFR 589.2001(b)(1)(vi)). A foreign country seeking this designation will submit a written request to FDA that includes a variety of information about the countries' BSE status (21 CFR 589.2001(f)). FDA estimates that 10 countries could submit a request to FDA to be exempted from CMPAF restrictions.

FDA estimates the reporting burden for this information collection as follows:

TABLE 2—ESTIMATED ONE-TIME AND RECURRING REPORTING BURDEN [1]

| 21 CFR Section | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| 589.2001(b)(1) [2] | 10 | 1 | 10 | 80 | 800 |
| 589.2001(f) | 10 | 1 | 10 | 26 | 260 |

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

[2] One-time burden.

Dated: October 14, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–27020 Filed 10–18–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2011–N–0002]**

### Cellular, Tissue and Gene Therapies Advisory Committee; Notice of Meeting

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

**ACTION:** Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

*Name of Committee:* Cellular, Tissue and Gene Therapies Advisory Committee.

*General Function of the Committee:* To provide advice and recommendations to the Agency on FDA's regulatory issues.

*Date and Time:* The meeting will be held on November 17, 2011, from 8:30 a.m. to 5 p.m.

*Location:* Hilton Washington, DC/Silver Spring, 8727 Colesville Rd., Silver Spring, MD 20910, 301–589–5200. For those unable to attend in person, the meeting will also be available by Web cast. On September 22, 2011, the link for the Web cast is available at *http://fda.yorkcast.com/webcast/Viewer/?peid=041ef376b14f4599be568b1b2893e85d1d.*

*Contact Person:* Gail Dapolito or Sheryl Clark, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC, area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

*Agenda:* On November 17, 2011,the committee will discuss Apligraf (Oral), Organogenesis, Inc., BLA 125400, for the treatment of surgically created gingival and alveolar mucosal surface defects in adults.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

*Procedure:* Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 9, 2011. Oral presentations from the public will be scheduled between approximately 11:35 p.m. and 12:35 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 1, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 2, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Gail Dapolito at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: October 12, 2011.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2011–27038 Filed 10–18–11; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2009–N–0026]**

### Apothecon et al.; Withdrawal of Approval of 103 New Drug Applications and 35 Abbreviated New Drug Applications; Correction

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

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of February 11, 2009 (74 FR 6896). The document withdrew approval of 103 new drug applications (NDAs) and 35 abbreviated new drug applications (ANDAs) from multiple applicants. The document inadvertently withdrew approval of NDA 50–435 for GEOCILLIN (carbenicillin indanyl sodium) Tablets held by Pfizer, Inc., 235 East 42d St., New York, NY 10017. FDA confirms that approval of NDA 50–435 is still in effect.

**FOR FURTHER INFORMATION CONTACT:** Florine Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

**SUPPLEMENTARY INFORMATION:** In FR Doc. E9–2901, appearing on page 6896, in the **Federal Register** of Wednesday, February 11, 2009, the following correction is made:

1. On page 6900, in the table, the entry for NDA 50–435 is removed.

Dated: September 30, 2011.

**Janet Woodcock,**

*Director, Center for Drug Evaluation and Research.*

[FR Doc. 2011–26967 Filed 10–18–11; 8:45 am]

**BILLING CODE 4160–01–P**