indicated that there was not enough information provided about the design and methodology of the pretests and the studies to effectively comment on the collection of information. In response, the information collection is for a broad spectrum of pretests and studies using a variety of methodologies and is dependent on the material being tested and the target audience. Each separate collection and pretest will be submitted for OMB review and approval prior to the collection or pretest being released to the public.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Individual In-Depth Interviews	360	1	360	0.75 (45 minutes)	270
General Public Focus Group Interviews.	144	1	144	1.5 hours	216
Intercept Interviews: Central Location.	600	1	600	0.25 (15 minutes)	150
Intercept Interviews: Telephone [2]	10,000	1	10,000	0.08 (5 minutes)	800
Self-Administered Surveys	2,400	1	2,400	0.25 (15 minutes)	600
Gatekeeper Reviews	400	1	400	0.50 (30 minutes)	200
Omnibus Surveys	2,400	1	2,400	0.17 (10 minutes)	408
Total (General Public)	16,304				2,644
Physician Focus Group Interviews	144	1	144	1.5 hours	216
Total (Physician)	144				216
Total (Overall)	16,448				2,860

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Brief interviews with callers to test message concepts and strategies following their call-in request to the FDA Center for Tobacco Products 1–800 number.

The number of respondents to be included in each new pretest will vary, depending on the nature of the material or message being tested and the target audience. However, for illustrative purposes, table 1 provides examples of the types of studies that may be administered and estimated burden levels that may be incurred during each year of the 3-year period. Time to read, view, or listen to the message being tested is built into the ''Hours per Response'' figures.

Dated: January 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01445 Filed 1–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0032]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008

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 February 25, 2013.

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 0910–0659 and title, ''Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User Fee Amendments of 2008.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@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. Antimicrobial Animal Drug Distribution Reports Under Section 105 of the Animal Drug User

Fee Amendments of 2008—(OMB Control Number 0910–0659)—Extension

Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA II) (Pub. L. 316) amended section 512 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360b) by, among other things, creating section 512(l)(3) to require that the sponsor of each new animal drug that contains an antimicrobial agent submit an annual report to FDA on the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals, including information on any distributor-labeled product. The legislation was enacted to address the problem of antimicrobial resistance and to help ensure that FDA has the necessary information to examine safety concerns related to the use of antibiotics in food-producing animals (154 Congressional Record H7534).

Each report must specify: (1) The amount of each antimicrobial active ingredient by container size, strength,

and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product. The first report under the statute was to be submitted not later than March 31, 2010.

The report covered the period of the preceding calendar year and included separate information for each month of the calendar year.

We are now seeking to further implement the statutory requirements of ADUFA II and enhance its public health and safety mission as envisioned by Congress by introducing an electronic form for the submission of the required annual reports under ADUFA II. The e-form FDA 3744a will enable sponsors to submit electronically and capture all information as mandated by Section 105 of ADUFA II. Form FDA 3744 will continue to be designated for paper submissions.

List of information required on form FDA 3744 and e-form FDA 3744a:

- Application Type
- Application Number
- Firm Name
- Dosage Form(s)
- Production Class(es)
- Animal Species—Food Animal or Food and Non-Food Animal
- Indications
- Active Ingredient(s)
- Domestic Quantities
  - Unit of Measure for All Active Ingredients
  - Calendar Year
  - Quantity Sold by Month for All Active Ingredients
  - Annual Total Sold for All Active Ingredients
- Export Quantities
  - Unit of Measure for All Active Ingredients
  - Calendar Year
  - Quantity Sold by Month for All Active Ingredients
  - Annual Total Sold for All Active Ingredients
- Individual Product Information for All Active Ingredients
  - Dosage Form
  - Container Size
  - Container Units
  - Active Ingredient Strength
- Quantities of Individual Products Sold or Distributed (Domestic and Export)
  - Unit of Measure for All Active Ingredients
  - Quantity Sold by Month for All Active Ingredients
  - Annual Total Sold for All Active Ingredients

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C Act section 512(1)(3)	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Capital costs
Annual Reports for Sponsors With Active Applications—Paper Submission.	3744	14	5.9	83	60	4,980	$6,975
Annual Reports for Sponsors With Active Applications—Electronic Submission.	e-Form 3744a	12	6.7	80	50	4,000	0
Annual Reports for Sponsors With Inactive Applications—Paper Submission.	3744	13	6.2	81	2	162	0
Annual Reports for Sponsors With Inactive Applications—Electronic Submission.	e-Form 3744a	11	7.3	80	2	160	0
Total						9,302	$6,975

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

The total annual responses were calculated by multiplying the number of respondents times the number of responses per respondent. Total burden hours were calculated by multiplying total annual responses times the average burden per response. As explained in the supporting statement for the subject collection of information (OMB control number 0910–0659), the initial one-time capital costs are for the design of the report. Here, e-form FDA 3744a and reporting via the Electronic Submission Gateway are provided by FDA. Thus, the remaining cost, as described in approved OMB control number 0910–0659 is $6,975 per year (3 hours × $46.50 wage rate × 50 sponsors) = $6,975. FDA believes that the sponsors already possess the computer equipment needed to prepare the report so that additional capital expenditures will not be necessary.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR 514.80(b)(5)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records and reports concerning experience with approved new animal drugs—special drug experience report	34	1	34	2	68

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

Total annual records were calculated by multiplying the number of recordkeepers times the number of records per recordkeeper. Total hours were calculated by multiplying total annual records times the average burden per recordkeeping.

In the **Federal Register** of January 17, 2012 (77 FR 2302), FDA published a 60-day notice requesting public comment on the proposed collection of information to which three comments were received: two from organizations and one from a member of Congress. The commenters generally supported the collection of sales data, and stated that this information would be useful in assessing antimicrobial drugs used in food-producing animals to better address the problem of antimicrobial resistance. One commenter stated that the information supplied by drug companies should be submitted in a format that would allow it to be easily merged with data from other FDA databases.

Beyond the scope of this **Federal Register** notice, all commenters recommended collection of antimicrobial use information in addition to the current requirements of ADUFA II sales reporting. All commenters also recommended revisions to the public reporting of the data being collected. The commenters requested FDA report sales of antimicrobial drug classes by month, by route of administration, by indication, by over-the-counter or prescription status, or grouped by their importance in human medicine. It was recommended that FDA collect and publicly report distribution information down to the state or regional level. ADUFA II requires that no class with fewer than three distinct sponsors of approved applications shall be independently reported; it was recommended that FDA seek additional authority from Congress to report sales figures for all antimicrobial classes regardless of the number of distinct drug sponsors. There was also a recommendation that all of the information collected be made publicly available in a searchable database.

FDA has considered the comments, but at this time we can only require the submission of information on the new e-form FDA 3744a that is expressly required to be submitted by section 512(l)(3) of the FD&C Act. We are pursuing notice and comment rulemaking to codify these requirements, and are currently assessing any additional data requirements. In this regard, FDA published an Advance Notice of Proposed Rulemaking on July 27, 2012, in which FDA solicited comment on the following: (1) Whether FDA should require submission of an estimate of the amount of antimicrobial ingredient sold or distributed for use in each approved food animal species, (2) how FDA can best compile and present required summary information, and (3) alternative methods there may be for obtaining additional data and information about the extent of antimicrobial drug use in food-producing animals and are there alternative methods the Agency can employ within its existing authority.

Dated: January 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01446 Filed 1–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Vaccines and Related Biological Products 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: Vaccines and Related Biological Products 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 February 27, 2013 between approximately 8:30 a.m. and 2:45 p.m.

Location: National Institutes of Health (NIH) Fishers Lane Conference Center, Terrace Level, Rooms 508–510, 5635 Fishers Lane, Rockville, MD, 20852. Please enter the building through the main front entrance on Fishers Lane and take the elevators down to the T-Terrace Level. For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at *http://videocast.nih.gov.*

Contact Person: Donald W. Jehn or Denise Royster, 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). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On February 27, 2013, the committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2013–2014 influenza season.

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 meeting 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 February 20, 2013. Oral presentations from the public will be scheduled between approximately 12:35 p.m. and 1:35 p.m. Those individuals interested in making