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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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) (Public Law 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.	No. of Respondents	No 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	e-Form 3744a	12	6.7	80	50	4,000	0

Sponsors With Active Applications --Electronic Submission							
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)	No. of Recordkeepers	No. 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.

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