5A002 ''Information security'' systems, equipment ''components'' therefor, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Related Controls: * * * (4) ''Systems,'' ''equipment'' and ''components'' described under ECCNs 4A005 or 5A001.j are classified under ECCNs 4A005 or 5A001.j, even if the ''systems,'' ''equipment'' or ''components'' are designed or modified to use ''cryptography'' or cryptanalysis.

* * * * *

■ 24. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 5 Part 2, ECCN 5D002 is amended by adding paragraph (3) to the Related Controls paragraph in the List of Items Controlled section to read as follows:

5D002 ''Software'' as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Related Controls: * * * (3) ''Software'' described under ECCN 4D001.a (''specially designed'' or modified for 4A005 or 4D004), 4D004, 5D001.a (''specially designed'' or modified for 5A001.j) or 5D001.c (''specially designed'' or modified for 5A001.j or 5B001.a) is classified under those ECCNs, even if the ''software'' is designed or modified to use ''cryptography'' or cryptanalysis.

* * * * *

■ 25. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 5 Part 2, ECCN 5E002 is amended by revising the Related Controls paragraph in the List of Items Controlled section to read as follows:

5E002 ''Technology'' as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Related Controls: (1) See also 5E992. This entry does not control ''technology'' ''required'' for the ''use'' of equipment excluded from control under the Related Controls paragraph or the Technical Notes in ECCN 5A002 or ''technology'' related to equipment excluded from control under ECCN 5A002. This ''technology'' is classified as ECCN 5E992. (2) ''Technology'' described under ECCN 4E001.a (''required'' for equipment in 4A005 or ''software'' in 4D004), 4E001.c, or 5E001.a (''required'' for 5A001.j or 5D001.a) that is designed or modified to use ''cryptography'' or cryptanalysis is classified under ECCNs 4E001.a or .c, or ECCN 5E001.a, respectively.

* * * * *

Dated: May 11, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–11642 Filed 5–19–15; 8:45 am]

BILLING CODE 3351–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA–2012–N–0447; 0910–AG45]

Antimicrobial Animal Drug Sales and Distribution Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Animal Drug User Fee Amendments of 2008 (ADUFA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to require that sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient submit an annual report to the Food and Drug Administration (FDA or Agency) on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals, and further requires FDA to publish annual summary reports of the data it receives from sponsors. At this time, FDA is issuing proposed regulations for the administrative practices and procedures for animal drug sponsors who must report under this law. This proposal also includes an additional reporting provision intended to enhance FDA's understanding of antimicrobial animal drug sales intended for use in specific food-producing animal species.

DATES: Submit either electronic or written comments on the proposed rule by August 18, 2015. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by June 19, 2015 (see the ''Paperwork Reduction Act of 1995'' section of this document).

ADDRESSES: You may submit comments by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section).

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following way:

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

Instructions: All submissions received must include the Docket No. FDA–2012–N–0447 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9062, *Neal.Bataller@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of Proposed Rule

Section 105 of ADUFA (ADUFA 105) amended section 512 of the FD&C Act (21 U.S.C. 360b) to require that sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient submit an annual report to FDA on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals. ADUFA 105 also requires FDA to publish annual summary reports of the data it receives. In accordance with the new law, sponsors of the affected antimicrobial new animal drug products began submitting their sales and distribution data to FDA on an annual basis, and FDA published summaries of such data for each calendar year beginning with 2009. The purpose of this rulemaking is to amend the Agency's existing records and reports regulation in part 514 (21 CFR part 514) to incorporate the sales and distribution data reporting requirements specific to antimicrobial new animal drugs that were added to the FD&C Act by ADUFA 105. This proposal also includes an additional reporting provision intended to further enhance FDA's understanding of antimicrobial animal drug sales

intended for use in specific food-producing animal species.

Summary of Major Provisions

The proposed rule, if finalized, will amend the records and reports regulation in part 514 to include the following:

- Procedures relating to the submission to FDA of annual sales and distribution data reports by sponsors of approved new animal drug products sold or distributed for use in food-producing animals. The proposal includes specific reporting criteria, including the requirement that sponsors submit species-specific estimates of product sales as a percentage of total sales.
- Procedures applicable to FDA's preparation and publication of summary reports on an annual basis based on the sales and distribution data it receives from sponsors of approved antimicrobial new animal drug products. The proposal includes specific parameters for the content of the annual summary reports as well as provisions intended to protect confidential business information and national security, consistent with ADUFA 105.
- Provisions that will give sponsors of approved new animal drug products containing antimicrobial active ingredients that are sold or distributed for use in food-producing animals the opportunity to avoid duplicative reporting of product sales and distribution data to FDA under part 514.

Costs and Benefits

FDA estimates one-time costs to industry from this proposed rule, if finalized, at about $138,800. FDA estimates annual costs at about $55,700. These costs equate to an estimated total annualized cost of about $75,400 at a 7 percent discount rate over 10 years and about $71,900 at a 3 percent discount rate over 10 years. The total annualized costs include the administrative cost to review the rule ($9,700), plus the cost to those sponsors who wish to avoid duplicative reporting requirements under part 514 ($4,800), plus the cost of providing the species-specific estimate of the percent of the drug product distributed domestically ($61,000).

The proposed rule would provide some flexibility for the manner in which new animal drug sponsors report the sales and distribution data under both § 514.80 and proposed § 514.87, by allowing for only one set of report submissions under certain circumstances. FDA estimates that this will reduce labor costs for new animal drug sponsors by $100,200 annually.

Another benefit of this proposed rule would be the cost savings associated with reporting monthly sales and distribution data to FDA in terms of product units rather than calculating the amount of antimicrobial active ingredients associated with these monthly product sales and distribution data. FDA estimates the calculation reductions would amount to an annual benefit of about $18,600. FDA estimates total annual benefits at about $118,800.

I. Background

Section 105 of ADUFA (Pub. L. 110–316) amends section 512(*l*) of the FD&C Act by adding new section 512(*l*)(3). Section 512(*l*) of the FD&C Act requires sponsors of approved or conditionally approved new animal drug applications to establish and maintain records and make such reports to FDA of data and other information relating to experience with their new animal drugs as required by regulation or order. Under new section 512(*l*)(3) of the FD&C Act, sponsors of antimicrobial new animal drugs approved for use in food-producing animals must submit to FDA on an annual basis a report specifying the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals. Specifically, sponsors are required to report the amount of each antimicrobial active ingredient as follows: (1) By container size, strength, and dosage form; (2) by quantities distributed domestically and quantities exported; and (3) for each dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product. The information must be reported for the preceding calendar year, include separate information for each month of the calendar year, and be submitted to FDA each year no later than March 31. Section 512(*l*)(3) of the FD&C Act also requires FDA to publish an annual summary report of the antimicrobial drug sales and distribution data collected from the drug sponsors, and further provides that such data must be reported by antimicrobial class.

The first reporting year under new section 512(*l*)(3) of the FD&C Act was calendar year 2009. In accordance with the new law, sponsors of affected new animal drug products submitted their 2009 sales and distribution data to FDA by March 31, 2010, and FDA published a summary report of these data later that same year. To date, FDA has collected sales and distribution data, and published summary reports of such data, for each calendar year from 2009 through and including 2012. As noted earlier, the purpose of this rulemaking is to amend FDA's animal drug records and reports regulation at part 514 to include administrative practices and procedures for sponsors of antimicrobial new animal drugs sold or distributed for use in food-producing animals who must report annually under section 512(*l*)(3) of the FD&C Act, including a proposed provision intended to enhance understanding of antimicrobial new animal drug sales intended for use in specific food-producing animal species. Collecting species-specific data is expected to assist FDA in assessing antimicrobial sales trends in the major food-producing animal species and examining how such trends may relate to antimicrobial resistance. Having improved data would also support this Agency's ongoing efforts to encourage the judicious use of antimicrobials in food-producing animals to help ensure the continued availability of safe and effective antimicrobials for animals and humans.

FDA previously issued an advance notice of proposed rulemaking (ANPRM) to obtain public input on potential amendments to its animal drug records and reports regulation at part 514, including the proposed provision to require data about specific food-producing animal species discussed in this document. The comments FDA received in response to the ANPRM were considered in preparing this proposed rule.

II. Proposed Regulations

A. Records and Reports—Conforming Changes (Proposed § 514.80(b)(4)(i))

Under current § 514.80(b)(4) of the Agency's regulations, sponsors of approved new animal drugs are required to submit a periodic drug experience report to FDA. Such reports include information regarding known adverse drug experiences, study reports from any recently conducted laboratory or clinical studies, current product labeling, and, under paragraph (b)(4)(i), product distribution data. In order to avoid duplicative reporting, FDA proposes that applicants submitting annual sales and distribution reports for antimicrobial new animal drug products under proposed § 514.87 would have the option to choose not to report distribution data under current § 514.80(b)(4)(i) for their approved applications that include these same products. However, this exemption from reporting under § 514.80(b)(4)(i) would only apply provided the following proposed conditions are met:

- Applicants would have to submit complete periodic drug experience

reports under § 514.80(b)(4), including paragraph (b)(4)(i), for such applications for at least 2 full years after the date of the initial approval of their drug product application, in addition to the reporting that would be required under proposed § 514.87. Under current § 514.80(b)(4), applicants of newly approved applications must submit periodic drug experience reports every 6 months for the first 2 years and such reporting is only required annually after that. This requirement provides FDA with enhanced drug experience feedback on newly approved animal drug products for which the Agency and animal drug industry have less practical experience compared to mature animal drug products that have been marketed for 2 or more years. In contrast, proposed § 514.87, which implements recently added section 512(*l*)(3) of the FD&C Act, would only require sales and distribution reports for antimicrobial new animal drug products once per year. By retaining the requirement that applicants of such drug products submit complete periodic drug experience reports at 6-month intervals under § 514.80(b)(4) for 2 full years after the date of the initial approval of their drug product application, this proposal would assure that enhanced drug experience surveillance for newly approved products is maintained.

- Applicants who wish to have the option of not providing distribution data as part of the periodic drug experience reports they submit under current § 514.80(b)(4)(i) for those approved applications that include the same antimicrobial new animal drug products that are covered by the reporting requirements under proposed § 514.87 would have to assure that the beginning of the reporting period for the annual periodic drug experience reports for such applications is January 1. Under § 514.80(b)(4), the reporting period and submission deadline of yearly periodic drug experience reports is tied to the anniversary date of the drug's approval unless the applicant petitions for, and is granted, approval to change the reporting timeframes. For approved applications that have a reporting period that begins on a date other than January 1, applicants would submit a one-time request to change the submission date for their yearly (annual) periodic drug experience report such that the reporting period begins on January 1 and ends on December 31, as currently provided for in § 514.80(b)(4). Such requests may be made at any time, but, consistent with the timeframe discussed in the previous paragraph, FDA will only grant such requests after at least 2 full years have elapsed since the date of the initial approval of the subject application. In accordance with section 512(*l*)(3) of the FD&C Act, reporting of antimicrobial drug sales and distribution data under proposed § 514.87 would be by calendar year. The purpose of having affected applicants assure that the reporting period for their annual periodic drug experience reports begins on January 1 is so that the reporting periods for all annual reports submitted under part 514 for a particular application will be consistent and cover the same time period beginning January 1 of each year, regardless of whether submitted under § 514.80(b)(4) or proposed § 514.87.
- Once an applicant has changed the submission date to align with the reporting period for proposed § 514.87 (beginning January 1 of each year), the Agency would also expect the applicant to submit, on a one-time basis, a special drug experience report as described in current § 514.80(b)(5)(i), that would address any gaps in distribution data caused by the change in reporting periods.
- Sponsors who hold approved applications for antimicrobial new animal drugs intended for use in food-producing animals who choose not to separately report distribution data for their products under § 514.80(b)(4)(i) would have to assure that full sales and distribution data for each product approved under such applications are alternatively reported under proposed § 514.87, including products approved under such applications that are labeled only for use in nonfood-producing animals. This would assure that all distribution data for every drug product under approved applications for antimicrobial new animal drugs intended for use in food-producing animals are reported to FDA and that all such data are reported under one regulation, proposed § 514.87.

FDA also proposes to revise § 514.80(b)(4) by extending the deadline for submission of annual periodic drug experience reports from within 60 days to within 90 days of the anniversary date of the approval. For those applicants whose reporting period under § 514.80(b)(4) begins on January 1—either because the anniversary of the drug application's approval falls on that date or because the applicant petitions for, and is granted, a new submission date that aligns the reporting period under § 514.80(b)(4) with the reporting period under proposed § 514.87 (*i.e.,* beginning January 1 of each year)—this revision would harmonize the timeframe for submitting annual periodic drug experience reports following the close of the reporting period with the 90-day timeframe sponsors have to submit annual antimicrobial animal drug sales and distribution reports for the preceding calendar year (by no later than March 31) as required by section 512(*l*)(3) of the FD&C Act.

B. Annual Sponsor Reports of Antimicrobial Animal Drug Sales and Distribution Information (Proposed § 514.87(a) Through (e))

Proposed paragraph (a) would reflect the requirement, under section 512(*l*)(3) of the FD&C Act, for each sponsor of a new animal drug product that is approved or conditionally approved and contains an antimicrobial active ingredient, to report to FDA on an annual basis the amount of each antimicrobial active ingredient in the drug product that is sold or distributed for use in food-producing animals. This includes products that are the subject of an approved new animal drug application or abbreviated new animal drug application, as well as products that are conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). Proposed paragraph (a) would also incorporate the requirement from section 512(*l*)(3) of the FD&C Act for animal drug sponsors to capture in their sales and distribution data reports information regarding any distributor-labeled products (see section 512(*l*)(3)(A) of the FD&C Act).

Proposed paragraph (b) sets out what information would need to be included in the drug sponsor's annual report in order to satisfy paragraph (a). Specifically, proposed paragraph (b) would require each annual report to identify the approved or conditionally approved application for the subject antimicrobial new animal drug product and include the following product-specific information (see section 512(*l*)(3)(B) and (C)(iii) of the FD&C Act):

- A listing of each antimicrobial active ingredient contained in the product;
- a description of each unique marketed product by unit (*i.e.,* container size, strength, and dosage form);
- for each such product, a listing of the target animal species, indications, and production classes that are specified on the approved label;
- for each such product, the number of units sold or distributed in the United States (*i.e.,* domestic sales) for each month of the reporting year; and
- for each such product, the number of units sold or distributed outside the United States (*i.e.,* quantities exported) for each month of the reporting year.

Currently, animal drug sponsors are complying with the requirements of section 512(*l*)(3) of the FD&C Act through a two-step process. First, they collect monthly sales and distribution data for their affected new animal drug products in terms of unit sales. Then they calculate the amount of antimicrobial active ingredients associated with those product sales and report those figures to FDA. After several years of collecting and collating sales and distribution data under section 512(*l*)(3) of the FD&C Act, FDA believes the most effective and efficient method for achieving the goals of this statutory provision is for animal drug sponsors to limit their annual reporting to product sales and distribution data in terms of unit sales, and then FDA can use that information to calculate the exact amounts of antimicrobial active ingredients associated with those product sales. Animal drug sponsors are very experienced at collecting and reporting accurate sales and distribution data in terms of units of product sold or distributed because of their current obligation to annually report such information to FDA in their periodic drug experience reports under § 514.80(b)(4). However, our experience has shown great variability in reporting accuracy when sponsors are asked to convert product sales data into active ingredient sales data. Such variability causes confusion for the Agency and requires more time to verify submitted data with sponsors. Therefore, FDA believes this approach will not only reduce the burden on both the sponsors and the Agency, but will greatly increase the accuracy of the final results.

The Agency also believes a ''reporting by product'' approach is consistent with the requirements of ADUFA 105. Section 512(*l*)(3)(B) of the FD&C Act acknowledges that antimicrobial active ingredients are sold and distributed as products through its requirement that sponsors report their antimicrobial data by, among other things, ''container size, strength, and dosage form,'' and, ''for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product.'' The container size, strength, and dosage form define a unique marketed product within an approved or conditionally approved application; therefore, under this proposal, if finalized, drug sponsors subject to the ADUFA 105 reporting requirements would need to continue to provide separate antimicrobial sales and distribution data for each of these unique marketed products in their reports. With knowledge of all the unique marketed products within an approved or conditionally approved application, along with the unit sales and distribution data for each of these products, the amount of antimicrobial active ingredient associated with those sales can then be calculated. The only question is who will perform the calculations and, as noted earlier, FDA believes that the Agency is best suited to perform this function in order to maximize accuracy and efficiency.

Further, proposed paragraph (b) would require the sponsor of an approved or conditionally approved antimicrobial new animal drug product to list in its annual report the target animals, indications, and production classes that are specified on the approved label of each unique product. FDA believes this requirement is consistent with the reporting requirements added to the FD&C Act by ADUFA 105. Section 512(*l*)(3)(B) of the FD&C Act provides for sponsors to report their antimicrobial data by, among other things, container size, strength, and dosage form and, ''for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product.'' As previously stated, the container size, strength, and dosage form define a unique marketed product within an approved or conditionally approved application. The dosage form is part of what defines a unique marketed product; thus, listing the target animals, indications, and production classes that are specified on the approved label of each unique product provides the information required by ADUFA 105.

Proposed paragraph (c) would require that each annual report to FDA provide a species-specific estimate of the percentage of each new animal drug product containing an antimicrobial active ingredient that was sold or distributed domestically for use in cattle, swine, chickens, or turkeys, but only if such animal species appears on the approved label. This provision is not intended to require animal drug sponsors to conduct studies of on-farm drug use practices. FDA believes that animal drug sponsors have access to information obtained in the ordinary course of their business (for example, through marketing activities) to estimate the percentage of annual product sales that are sold or distributed domestically for use in any of these four major food-producing species that appear on the approved product label. While certain products may be legally used in an extralabel manner, promotion of such extralabel use is prohibited, and FDA believes that drug sponsors are unlikely to possess meaningful data on the percentage of their products that may be sold for extralabel use, especially for species not on the product label. If, however, a sponsor *is* aware of extralabel product sales for use in any of the four major food-producing species listed on the product's label, these sales would be included in deriving the estimate reported under proposed paragraph (c) for that species.

The Agency believes having species-specific estimates of product sales and distribution for use in the four major food-producing categories of animal species (cattle, swine, chickens, turkeys) would be important in supporting efforts such as the National Antimicrobial Resistance Monitoring System (NARMS), a surveillance program that monitors trends in antimicrobial resistance among foodborne bacteria from humans, retail meats, and animals. NARMS retail meat and animal sampling focus on the same four major food-producing species proposed here. Since there is currently limited resistance data related to minor food-producing animals and companion animals, requiring estimates of these additional species would cause additional burden without clear benefit.

In order to assure that the total of the species-specific percentages reported for each product adds up to 100 percent of its sales and distribution, a fifth category for ''other species/unknown'' would also be included in this provision. This category would be used to capture the percentage of each new animal drug product that was sold or distributed for use in animal species other than the four major food-producing species or otherwise unknown to the reporting drug sponsor.

The following hypothetical scenarios are presented here as illustration:

- An antimicrobial product is approved for use only in cattle and swine, and the sponsor estimates that 100 percent of the annual sales were for use in cattle. In this situation, the sponsor would report: Cattle 100 percent, swine 0 percent, chickens 0 percent, turkeys 0 percent, other species/unknown 0 percent.
- An antimicrobial product is approved for use only in cattle and swine, and the sponsor estimates that 50 percent of the annual sales were for use in cattle, 30 percent were for use in swine, and 20 percent were unknown to the sponsor. In this situation, the sponsor would report: Cattle 50 percent, swine 30 percent, chickens 0 percent, turkeys 0 percent, other species/unknown 20 percent.

• An antimicrobial product is approved for use only in cattle, sheep, and dogs, and the sponsor estimates that 50 percent of the annual sales were for use in cattle, 10 percent were for use in sheep, and 40 percent were for use in dogs. Since dogs are companion animals and sheep are a minor species, sales estimates for these would be reported together in the ''other species/unknown'' category. Thus, in this situation, the sponsor would report: Cattle 50 percent, swine 0 percent, chickens 0 percent, turkeys 0 percent, other species/unknown 50 percent.

As noted earlier, under this proposal, sponsors who hold approved applications for antimicrobial new animal drugs intended for use in food-producing animals who choose not to separately report distribution data for their products under § 514.80(b)(4)(i) would have to assure that full sales and distribution data for each product approved under such applications are alternatively reported under proposed § 514.87, including products approved under such applications that are labeled only for use in nonfood-producing animals. In this situation, sponsors would report the species-specific estimate of sales for the products labeled only for use in nonfood-producing animals as 100 percent ''other species/unknown.''

All species-specific estimates would reflect domestic sales for the entire reporting year and would not include separate information for each month of the reporting year. ADUFA 105 requires drug sponsors to report sales and distribution data to FDA broken out by month; however, antimicrobial drug products may be used at any time up to several years after distribution. The Agency considers monthly fluctuations in drug product sales to be of limited value in reflecting when products may actually be administered to animals and interpreting antimicrobial resistance trends; therefore, FDA reports yearly sales and distribution information in its annual summary reports instead of monthly amounts. The Agency believes that requiring sponsors to report monthly species-specific estimates would entail a greater burden to drug sponsors without providing meaningful information.

Most antimicrobial new animal drug products that are approved for use in food-producing animals are labeled for use in more than one animal species, in some cases five or more species. Therefore, since the antimicrobial sales and distribution data reported to FDA by drug sponsors under section 512(*l*)(3) of the FD& Act are derived from drug product sales, very little can be concluded about antimicrobial sales intended for use in any one particular species for products that are approved for use in more than one species. The Agency believes having species-specific estimates of product sales and distribution for use in the four major food-producing categories of animal species (cattle, swine, chickens, turkeys) would be important in supporting efforts such as NARMS, a surveillance program that tracks trends related to antimicrobial resistance in food-producing animals and humans. FDA believes that this additional sales and distribution information would be useful to better understand how the use of medically important antimicrobial drugs in food-producing animals may contribute to the emergence or selection of antimicrobial resistant bacteria. Specifically, this information could inform microbial food safety risk assessments by providing a better indication of the extent to which a drug or drug class is used in a specific food animal species by a specific route of administration. From this, it may be possible to draw conclusions about how antimicrobial sales and distribution data compare with data from NARMS. In addition, such information could further enhance FDA's ongoing activities related to slowing the development of antimicrobial resistance and is consistent with the recommendations in guidance recently issued by this Agency addressing the judicious use of medically important antimicrobial drugs in food-producing animals (Guidance for Industry #209, entitled ''The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals'').

Since it is likely that many sponsors would consider their species-specific sales and distribution estimates as proprietary information, and that such estimates may often be derived from proprietary marketing analyses, FDA would, as described in proposed paragraph (e), consider the species-specific information reported by individual sponsors under paragraph (c) to be confidential business information consistent with section 512(*l*)(3) of the FD&C Act and this Agency's regulations at 21 CFR 20.61.

Proposed paragraph (d) would incorporate the requirement specified in section 512(*l*)(3)(C) of the FD&C Act that each annual antimicrobial drug sales and distribution data report be submitted to FDA not later than March 31 of each year and cover the period of the preceding calendar year (see section 512(*l*)(3)(C)(i) and (ii) of the FD&C Act). Proposed paragraph (d) would also require that each such report be submitted to FDA using Form FDA 3744, ''Antimicrobial Animal Drug Distribution Report.''

C. Annual Summary Reports Published by FDA (Proposed § 514.87(f))

Proposed paragraph (f) would incorporate the requirement established by ADUFA 105 for FDA to publish an annual summary report of the antimicrobial drug sales and distribution data collected from drug sponsors by antimicrobial class (see section 512(*l*)(3)(E) of the FD&C Act). Consistent with the statute, this proposed paragraph would also require that FDA not independently report those antimicrobial classes with fewer than three distinct sponsors, and would further require that, in reporting the antimicrobial drug sales and distribution data it receives from drug sponsors, FDA must do so in a manner consistent with protecting both national security and confidential business information (see section 512(*l*)(3)(E)(i) and (ii) of the FD&C Act).

Proposed paragraph (f) would also require FDA to publish its annual summary report of the information it receives under this section for each calendar year by December 31 of the following year. Proposed paragraph (f) also provides that, in addition to summarizing sales and distribution data by antimicrobial drug class, the annual summary report may also include additional summaries of the data received under this section, as determined by FDA. For example, on October 2, 2014, FDA published annual summary reports that include additional data tables on the importance of each drug class in human medicine, the approved routes of administration for these antimicrobials, whether these antimicrobials are available over-the-counter or require veterinary oversight, and whether the antimicrobial drug products are approved for therapeutic purposes or for production purposes, or both therapeutic and production purposes.

Paragraph (f) also proposes that the publication of any summary data in addition to drug class would be limited by the same confidentiality and national security protections as is required by the statute, as noted previously, for the publication of summary data by drug class. Specifically, each individual datum appearing in the summary report, regardless of its classification or source, would be required to: (1) Reflect cumulative product sales and distribution data from three or more distinct sponsors of approved products that were actively sold or distributed that reporting year and (2) be reported

in a manner consistent with protecting both national security and confidential business information. This approach would make it possible to present sales and distribution data in a manner consistent with the confidentiality provisions of section 512(*l*) of the FD&C Act.[1]

III. Legal Authority

FDA's authority for issuing this proposed rule is provided by section 512(*l*) of the FD&C Act. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Preliminary Regulatory Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not an economically significant regulatory action as defined by Executive Order 12866.

FDA has developed a preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule to stakeholders and the government. The summary analysis of benefits and costs included in the Executive Summary of this document is drawn from the detailed PRIA, which is available at *http://www.regulations.gov* (Docket No. FDA–2012–N–0447), and is also available on FDA's Web site at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/Default.htm*.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given in the *Description* section that follows with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA 105) Regulation Information Collection.

Description: The ADUFA 105 legislation was enacted to address the problem of antimicrobial resistance and to help ensure safety related to the use of antibiotics in food-producing animals.

With these concerns in mind, Congress passed and the President signed ADUFA 105 in 2008, which amended section 512 of the FD&C Act to require that sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient submit an annual report to FDA on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals.

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 report must cover the period of the preceding calendar year and include separate information for each month of the calendar year.

ADUFA 105 also requires FDA to publish annual summary reports of the data it receives.

In accordance with the new law, sponsors of the affected antimicrobial new animal drug products have submitted their sales and distribution data to FDA, and FDA has published summaries of such data, for each calendar year since 2009.

The proposed rule, if finalized, will amend the records and reports regulation in part 514 to include the following:

- Procedures relating to the submission to FDA of annual sales and distribution data reports by sponsors of approved new animal drug products sold or distributed for use in food-producing animals. The proposal includes specific reporting criteria, including the requirement that sponsors submit species-specific estimates of product sales as a percentage of total sales.
- Procedures applicable to FDA's preparation and publication of summary reports on an annual basis based on the sales and distribution data it receives from sponsors of approved antimicrobial new animal drug products. The proposal includes specific parameters for the content of the annual summary reports as well as provisions intended to protect confidential business information and national security, consistent with ADUFA 105.
- Provisions that will give sponsors of approved new animal drug products containing antimicrobial active ingredients that are sold or distributed for use in food-producing animals the opportunity to avoid duplicative reporting of product sales and distribution data to FDA under part 514.

Description of Respondents: Animal Drug Manufacturers (Sponsors).

This proposed rule would, among other things, revise existing OMB control number 0910–0659 (expiration date November 30, 2016) for antimicrobial drug products under ADUFA 105 by codifying statutory provisions. Many of the provisions of the information collection will not be affected by the proposed rule, if finalized. Therefore, this PRA section will concentrate on the changes being proposed in this rulemaking and will describe how the paperwork reduction implications will be affected.

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

Proposed Reporting Requirement—One-Time Reporting Burden and Costs

Because the information collection requirements of ADUFA 105 have been in effect for some time (the first report sponsors submitted was for calendar year 2009), one-time capital costs for the design of the report by firms have already occurred and need not be reported here.

In addition, the paper Form FDA 3744, the e-Form FDA 3744a, and

[1] It should also be noted that the Trade Secrets Act, 18 U.S.C. 1905, a broadly worded criminal statute, also imposes obligations on the Agency to protect confidential business information, including that obtained from the drug sponsors. A violation of the Trade Secrets Act can carry criminal penalties.

reporting via the Electronic Submission Gateway are provided by FDA at no cost. Thus, there is no one-time capital cost for report design or forms under the provisions of the proposed rule, and FDA considers the possession of computers and Internet accessibility to be usual and customary business practices.

Table 1 provides the one-time costs for the proposed rule, if finalized, which is estimated at $138,800, about one-half of which is the unavoidable cost of reviewing the rule and developing a compliance plan. Current sponsors of approved or conditionally approved applications for antimicrobial new animal drugs sold or distributed for use in food-producing animals would need to review the rule; however, since the proposed rule would mostly codify current practices, sponsors would not require significant review time. FDA estimates that there are 34 sponsors total, 23 sponsors with active (*i.e.,* currently marketed) applications and 11 sponsors with only inactive applications, respectively, that would need to review the rule. This would require 24 hours each for the 23 active sponsors and 1 hour each for the 11 inactive sponsors. The sponsors with inactive applications would require less time to perform the review and would not need to develop the compliance plan. FDA estimates that one-half of the active sponsors would use personnel at the general and operations manager level ($134 per hour times 24 hours times 11.5 equals approximately $36,900). The other half of active sponsors would use an industrial production manager ($109 per hour times 11.5 times 24 hours equals approximately $30,100). (Please note that both estimates are rounded to be in accordance with the PRIA.) The total cost for review by sponsors of active approved applications is estimated at about $67,000.

For the one-time, 1-hour review of the rule for the 11 sponsors of inactive approved applications, FDA assigns one-half, or 5.5 hours, at the $134 per hour adjusted rate for general and operations managers, while one-half, or 5.5 hours, is assigned at the $109 adjusted rate for industrial production managers. The total cost for the review by sponsors of inactive approved applications is estimated at about $1,300 (rounded to be in accordance with the PRIA).

FDA estimates that the total administrative costs for rule review and compliance plan development to be about $68,300 ($67,000 + $1,300).

Benefits of Proposed § 514.87

The proposed rule would allow applicants submitting annual sales and distribution reports for antimicrobial new animal drug products under § 514.87 the option to not report distribution data under § 514.80(b)(4)(i)(A) for the approved applications that include these same products, but only provided certain conditions are met. One condition is that sponsors must ensure that the beginning of the reporting period for the annual periodic drug experience reports for such applications is January 1. For applications that currently have a reporting period that begins on a date other than January 1, applicants must request a change in reporting submission date for their annual periodic drug experience report such that the reporting period begins on January 1 and ends on December 31, as described in § 514.80(b)(4). A second, and related, condition, is that applicants that change their reporting submission date must also, on a one-time basis, submit a special drug experience report, as described in current § 514.80(b)(5)(i), that addresses any gaps in distribution data caused by the change in reporting periods.

FDA estimates that 90 percent of the sponsors currently marketing approved new animal drugs containing an antimicrobial active ingredient for use in food-producing animals would make the request to change the submission date such that the reporting period begins on January 1 and ends on December 31. There are 23 sponsors of 153 approved applications. Ninety percent of 153 applications equates to about 138 applications held by 21 sponsors. FDA estimates that it would take approximately 2 hours for personnel to meet the first two conditions, making the change of date request for each application and preparing the one-time special drug experience report for each application. This results in approximately 276 hours. At the overhead and other benefits-adjusted wage rate of about $134 per hour for general and operations managers for one-half of the hours, and at $109 per hour for industrial production managers for the other one-half of the hours, the one-time cost would be about $33,400 (rounded to be in accordance with the PRIA).

Costs of Proposed § 514.87

Proposed § 514.87(c) would require that each report containing the amount of antimicrobial ingredient that is sold or distributed contain a species-specific estimate of the percentage of each product that was sold or distributed domestically in the reporting year for use in any of the following animal species categories, but only for such species that appear on the approved label: Cattle, swine, chickens, turkeys. The total of the species-specific percentages reported for each product must account for 100 percent of its sales and distribution; therefore, a fifth category of ''other species/unknown'' must also be reported.

FDA estimates that an individual would spend about 5 hours complying with this requirement in the first year. (Subsequent years are estimated to require about 3 hours to comply.) The additional 2 hours in the first year is a one-time cost incurred as individual company personnel discuss and settle upon a method to calculate these species-specific estimates. With the labor split evenly over the two wage rates, these 2 hours amount to a one-time cost of about $37,100 for the 153 active applications.

TABLE 1—ESTIMATED ONE-TIME REPORTING BURDEN [1]

21 U.S.C. 360b(b)(1)	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Administrative Review of the Rule: Sponsors with Active Applications	23	1	23	24	552
Administrative Review of the Rule: Sponsors with Inactive Applications	11	1	11	1	11
Requesting a Change of Date and Submit Special Drug Experience Report to Avoid Duplicative Reporting	21	6.57	138	2	[2] 275
Report Species-Specific Estimate of Percent of Products Distributed Domestically	23	6.65	153	2	306

TABLE 1—ESTIMATED ONE-TIME REPORTING BURDEN [1]—Continued

21 U.S.C. 360b(b)(1)	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Total					1,144

[1] There are no capital costs or operating and maintenance costs associated with this information collection.
[2] Hourly burden estimate adjusted to be in accordance with the PRIA.

Proposed Reporting Requirements—Annual Hourly Burden and Costs Benefits of Proposed § 514.87

A benefit of the proposed rule is to provide some flexibility in which new animal drug sponsors report the sales and distribution data under both § 514.80 and proposed § 514.87 by allowing sponsors to meet two separate reporting obligations under part 514 with one set of report submissions under certain circumstances. FDA estimates that 90 percent of the sponsors currently marketing approved new animal drugs containing an antimicrobial active ingredient for use in food-producing animals would make the request to change the submission date such that the reporting period begins on January 1 and ends on December 31, as provided in proposed § 514.87. These 138 approved applications (90 percent of 152) would still have to account for the costs of data collection and preparation, but they would no longer be required to include distribution data along with the other information required in the Drug Experience Report (DER) under § 514.80(b)(4)(i). FDA estimates that the time saved per application from the removal of the requirement for the distribution data in the DER could be as much as 6 hours per application. Using the same adjusted wage rates and distribution of hours by adjusted wage rates (one-half of the total hours at each rate), the annual benefit of the reduction of 138 hours times an average of $121 per hour is about $100,200.[2]

Another benefit of this proposed rule would be the cost savings associated with reporting monthly product sales and distribution data to FDA rather than calculating the amount of antimicrobial active ingredients associated with these monthly product sales and distribution data. Proposed § 514.87, if finalized, would eliminate the need for sponsors to perform and report calculations of the amount of antimicrobial active ingredients associated with monthly product sales and distribution data. These data have shown a wide variability in accuracy, causing additional verification efforts for FDA personnel. Therefore, it would be more efficient for sponsors (and for FDA) if sponsors were to limit their annual reporting to product sales and distribution data. This would allow FDA to calculate the exact amounts of antimicrobial active ingredients associated with those product sales. FDA estimates that this would reduce the industry reporting effort by 1 hour per application. FDA estimates that 153 approved applications for antimicrobial new animal drugs that are currently marketed would be affected by this change in policy, resulting in 153 fewer compliance hours annually. At the overhead and other benefits-adjusted wage rate of about $134 per hour for general and operations manager for one-half of the hours, and at $109 per hour for industrial production managers for the other one-half of the hours, the annual cost saving would be about $18,600 (rounded to be in accordance with the PRIA).

FDA estimates total annual benefits of this proposed rule, if finalized, at about $118,800.

Costs of Proposed § 514.87

As stated previously, proposed § 514.87(c) would require that each report containing the amount of antimicrobial ingredient that is sold or distributed contain a species-specific estimate of the percentage of each product that was sold or distributed domestically in the reporting year for use in any of the following animal species categories, but only for such species that appear on the approved label: Cattle, swine, chickens, turkeys. The total of the species-specific percentages reported for each product must account for 100 percent of its sales and distribution; therefore, a fifth category of ''other species/unknown'' must also be reported. FDA estimates that affected sponsors will require about 3 hours to comply with this provision annually. FDA estimates that 153 approved, currently marketed applications containing antimicrobial drugs as active ingredients would be affected by this change in policy, resulting in 459 additional compliance hours annually. At the overhead and other benefits-adjusted wage rate of about $134 per hour for general and operations managers for one-half of the hours, and at $109 per hour for industrial production managers for the other one-half of the hours, the additional 459 hours results in an additional annual cost of approximately $55,700 (rounded to be in accordance with the PRIA).

Data for 2012 was submitted by 23 sponsors of 153 active applications for antimicrobial new animal drug products sold or distributed for use in food-producing animals. FDA estimates that 60 hours are currently required to collect the necessary data and prepare the submission to FDA for each of the estimated one-half of active applications for which data is submitted on a paper Form FDA 3744, for a total of 4,590 hours. FDA estimates that 50 hours are required to collect the necessary data and prepare the submission to FDA for each of the estimated one-half of active applications for which data is submitted on e-Form FDA 3744a, for a total of 3,825 hours. Thus, FDA estimates a total of 8,415 burden hours are currently needed for the 23 sponsors of 153 active applications to report to FDA. At the overhead and other benefits-adjusted wage rate of about $134 per hour for general and operations managers for one-half of the hours, and at $109 per hour for industrial production managers for the other one-half of the hours, the annual cost of reporting to FDA is currently approximately $1.02 million.

FDA estimates that under the proposed rule, if finalized, affected sponsors would need 62 hours to report the necessary data on a paper Form FDA 3744 and 52 hours to report via e-Form FDA 3744a (3 additional hours for the species-specific reporting requirement minus 1 hour for cessation of the requirement to calculate the amount of antimicrobial ingredients associated with monthly product sales and distribution data). The total annual burden hours for the 23 sponsors of the 153 active applications to report under the proposed rule, if finalized would be 8,721 hours (4,743 hours for one-half of the industry using paper Form FDA 3744 and 3,978 hours for one-half of the industry using e-Form FDA 3744a), an

[2] OMB control numbers 0910–0284 and 0910–0645.

additional 306 hours over the current hourly burden. At the overhead and other benefits-adjusted wage rate of about $134 per hour for general and operations managers for one-half of the hours, and at $109 per hour for industrial production managers for the other one-half of the hours, the total annual cost of reporting for the industry under the proposed rule, if finalized, would be approximately $1.06 million. The cost of the additional 306 hours needed to annually report under the proposed rule, if finalized, is approximately $37,100 (rounded to be in accordance with the PRIA).

The 2012 data also show 11 sponsors with only inactive applications for antimicrobial new animal drug products for use in food-producing animals. FDA estimates that sponsors of these inactive applications for antimicrobial drug products need 2 hours per application to prepare and submit a report stating that there were no products distributed for the year, a total of 196 inactive approved applications times 2 hours annually equals 392 hours. This burden estimate would not be affected by the proposed rule, if finalized, and thus is not included in the following table.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C. 360b(b)(1)	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average additional burden per response [2]	Total hours
Annual Reports for Sponsors With Active Applications	3744	23	6.65	153	2	306

[1] There are no capital costs and no operating and maintenance costs associated with this information collection.
[2] Average additional burden per response in hours is the marginal difference between the current burden of OMB control number 0910–0659 and the additional burden per response resulting from this proposed rule.

Current Recordkeeping Burden

FDA will not address the recordkeeping provisions of all affected sponsors (34), who prepare 1 report per year and spend 2 hours annually maintaining those records (68 hours total), because the number of burden hours would not be affected by the proposed rule, if finalized.

To ensure that comments on 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 title ''Animal Drug User Fee Amendments (ADUFA 105) Regulation Information Collection.''

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

VI. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

List of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 514 be amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 1. The authority citation for 21 CFR part 514 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 360ccc, 371, 379e, 381.

■ 2. Amend § 514.80 by revising the fifth sentence of paragraph (b)(4) and by revising paragraph (b)(4)(i) to read as follows:

§ 514.80 Records and reports concerning experience with approved new animal drugs.

* * * * *

(b) * * *

(4) * * * The yearly periodic drug experience reports must be submitted within 90 days of the anniversary date of the approval of the NADA or ANADA. * * *

(i) *Distribution data.*

(A) Information about the distribution of each new animal drug product, including information on any distributor-labeled product. This information must include the total number of distributed units of each size, strength, or potency (*e.g.,* 100,000 bottles of 100 5-milligram tablets; 50,000 10-milliliter vials of 5-percent solution). This information must be presented in two categories: Quantities distributed domestically and quantities exported.

(B) Applicants submitting annual sales and distribution reports for antimicrobial new animal drug products under § 514.87 have the option not to report distribution data under paragraph (b)(4)(i)(A) of this section for the approved applications that include these same products, but only provided

each of the following conditions are met:

(*1*) Applicants must have submitted complete periodic drug experience reports under this section for such applications for at least 2 full years after the date of their initial approval.

(*2*) Applicants must assure that the beginning of the reporting period for the annual periodic drug experience reports for such applications is January 1. For applications that currently have a reporting period that begins on a date other than January 1, applicants must request a change in reporting submission date such that the reporting period begins on January 1 and ends on December 31, as described in paragraph (b)(4) of this section.

(*3*) Applicants that change their reporting submission date must also submit a special drug experience report, as described in paragraph (b)(5)(i) of this section, that addresses any gaps in distribution data caused by the change in date of submission.

(*4*) Applicants who choose not to report under paragraph (b)(4)(i)(A) of this section must assure that full sales and distribution data for each product approved under such applications are alternatively reported under § 514.87, including products that are labeled for use only in nonfood-producing animals.

* * * * *

■ 3. Add § 514.87 to read as follows:

§ 514.87 Annual reports for antimicrobial animal drug sales and distribution.

(a) The applicant for each new animal drug product approved under section 512 of the Federal Food, Drug, and Cosmetic Act, or conditionally approved under section 571 of the Federal Food, Drug, and Cosmetic Act, and containing an antimicrobial active ingredient, must submit an annual report to FDA on the amount of each such antimicrobial active ingredient in the drug that is sold or distributed in the reporting year for use in food-producing animal species, including information on any distributor-labeled product.

(b) This report must identify the approved or conditionally approved application and must include the following information for each new animal drug product described in paragraph (a) of this section:

(1) A listing of each antimicrobial active ingredient contained in the product;

(2) A description of each product sold or distributed by unit, including the container size, strength, and dosage form of such product units;

(3) For each such product, a listing of the target animal species, indications, and production classes that are specified on the approved label;

(4) For each such product, the number of units sold or distributed in the United States (*i.e.,* domestic sales) for each month of the reporting year; and

(5) For each such product, the number of units sold or distributed outside the United States (*i.e.,* quantities exported) for each month of the reporting year.

(c) Each report must also provide a species-specific estimate of the percentage of each product described in paragraph (b)(2) of this section that was sold or distributed domestically in the reporting year for use in any of the following animal species categories, but only for such species that appear on the approved label: Cattle, swine, chickens, turkeys. The total of the species-specific percentages reported for each product must account for 100 percent of its sales and distribution; therefore, a fifth category of ''other species/unknown'' must also be reported.

(d) Each report must:

(1) Be submitted not later than March 31 each year;

(2) Cover the period of the preceding calendar year; and

(3) Be submitted using Form FDA 3744, ''Antimicrobial Animal Drug Distribution Report.''

(e) Sales and distribution data and information reported under this section will be considered to fall within the exemption for confidential commercial information established in § 20.61 of this chapter and will not be publicly disclosed, except that summary reports of such information aggregated in such a way that does not reveal information which is not available for public disclosure under this provision will be prepared by FDA and made available to the public as provided in paragraph (f) of this section.

(f) FDA will publish an annual summary report of the data and information it receives under this section for each calendar year by December 31 of the following year. Such annual reports must include a summary of sales and distribution data and information by antimicrobial drug class and may include additional summary data and information as determined by FDA. In order to protect confidential commercial information, each individual datum appearing in the summary report must:

(1) Reflect combined product sales and distribution data and information obtained from three or more distinct sponsors of approved products that were actively sold or distributed that reporting year, and

(2) Be reported in a manner consistent with protecting both national security and confidential commercial information.

Dated: May 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12081 Filed 5–19–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–140991–09]

RIN 1545–BJ08

Guidance Regarding the Treatment of Transactions in Which Federal Financial Assistance Is Provided

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations under section 597 of the Internal Revenue Code (the ''Code''). The proposed regulations, which will apply to banks and domestic building and loan associations (and related parties) that receive Federal financial assistance (''FFA''), will modify and clarify the treatment of transactions in which FFA is provided to such institutions. This document also invites comments from the public and requests for a public hearing regarding these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by August 18, 2015.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–140991–09), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–140991–09), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at *http://www.regulations.gov/* (IRS REG–140991–09).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Russell G. Jones, (202) 317–5357, or Ken Cohen, (202) 317–5367; concerning the submission of comments or to request a public hearing, Oluwafunmilayo (Funmi) P. Taylor, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION: