**(a) Applicability**

(1) This AD applies to the following helicopters, certificated in any category:

(i) Eurocopter Model AS332C, AS332L, AS332 L1, and AS332 L2 helicopters with a hoist beam, Part Number (P/N) 330A87–2345–00, –01, –02, –03, –04, –05, or –06, installed with a single or double hoist plate; and

(ii) Eurocopter Model SA330J helicopters with a hoist beam, P/N 330A87–2345–00, –01, –02, –03, –04, –05, or –06, installed with a single hoist plate.

**(b) Unsafe Condition**

The unsafe condition is defined as hoist cable jamming and subsequent cable failure, which could result in injuries or damage to the helicopter.

**(c) Comments Due Date**

Comments are due November 25, 2013.

**(d) Compliance**

You are responsible for performing each action required by this AD within the specified compliance time unless accomplished previously.

**(e) Required Actions**

(1) Before the next hoist operation:

(i) For all helicopters, install a placard in full view of the hoist operator that states: ''IN CASE OF CABLE JAM AGAINST STRUT DO NOT ATTEMPT TO RAISE OR LOWER LOAD''.

(ii) For helicopters with a hoist control electrical harness routed at the base of the hoist supporting strut:

(A) Disable the hoist pyrotechnic shear function.

(B) Install a placard on the instrument panel in full view of the flight crew that states:

''HOIST PYROTECHNIC SHEAR FUNCTION DISABLED''.

(C) Install a placard in full view of the hoist operator that states:

''HOIST PYROTECHNIC SHEAR FUNCTION DISABLED. IN CASE OF NECESSITY, CUT THE HOIST CABLE WITH THE SHEARS LOCATED IN THE CABIN.''

(iii) For helicopters listed in Paragraph (a)(1)(i) of this AD with a tray-mounted double hoist installed with the back-up electrical hoist power supply harness routed at the base of the hoist supporting strut, do one of the following:

(A) Install a hoist beam lower fitting protector in accordance with the Accomplishment Instructions, paragraph 2.B.2.b of Eurocopter Emergency Alert Service Bulletin No. 25.02.08, Revision 3, dated July 6, 2011 (EASB), and if a short footstep, P/N 332P21–9000–00 or 332P21–2052–01, is installed, also install the short footstep with lower side protector in accordance with the Accomplishment Instructions, paragraph 2.B.2.c.2, of the EASB; or

(B) Install two placards, one in full view of the flight crew and one in full view of the the hoist operator, that state:

''IN–FLIGHT OPERATION OF THE HOIST IS PROHIBITED.''

(2) Within 60 hours time-in-service:

(i) For helicopters listed in paragraph (a)(1)(i) of this AD without a tray-mounted double hoist installed with the back-up electrical hoist power supply harness routed at the base of the hoist supporting strut and without a right hand sliding door, P/N 332A22–1165–01, installed, do one of the following:

(A) Install a hoist beam lower fitting protecter in accordance with the Accomplishment Instructions, paragraph 2.B.2.b, of the EASB and if a short footstep, P/N 332P21–9000–00 or 332P21–2052–01, is installed, also install the short footstep with lower side protector in accordance with the Accomplishment Instructions, paragraph 2.B.2.c.2, of the EASB; or

(B) Install two placards, one in full view of the flight crew and one in full view of the hoist operator, that state:

''IN–FLIGHT OPERATION OF THE HOIST IS PROHIBITED.''

(ii) For helicopters listed in paragraph (a)(1)(i) of this AD with a right hand sliding door, P/N 332A22–1165–01, installed, do one of the following:

(A) Install a hoist beam lower fitting protector in accordance with the Accomplishment Instructions, paragraph 2.B.5, of the EASB; or

(B) Install two placards, one in full view of the flight crew and one in full view of the hoist operator, that state:

''IN–FLIGHT OPERATION OF THE HOIST IS PROHIBITED.''

(iii) For Model SA330J helicopters, do one of the following:

(A) Install a hoist beam lower fitting protector in accordance with the Accomplishment Instructions, paragraph 2.B.4, of Eurocopter Emergency Alert Service Bulletin No. 25.39, Revision 3, dated July 5, 2011; or

(B) Install two placards, one in full view of the flight crew and one in full view of the hoist operator, that state:

''IN–FLIGHT OPERATION OF THE HOIST IS PROHIBITED.''

(3) For any helicopter that has been modified per paragraph (e)(1)(iii)(A), (e)(2)(i)(A), (e)(2)(ii)(A), or (e)(2)(iii)(A) of this AD, do the following before the next hoist operation:

(i) Re-establish the hoist pyrotechnic shear function if disabled per paragraph (e)(1)(ii)(A).

(ii) Remove any placards if installed as required by paragraph (e)(1)(i), (e)(1)(ii)(B), (e)(1)(ii)(C), (e)(1)(iii)(B), (e)(2)(i)(B), (e)(2)(ii)(B), or (e)(2)(iii)(B).

**(f) Alternative Methods of Compliance (AMOCs)**

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Robert Grant, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone 817–222–5110; email *robert.grant@faa.gov*.

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office before operating any aircraft complying with this AD through an AMOC.

**(g) Additional Information**

The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2009–0271R1, dated July 8, 2011. You may view the EASA AD at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2013–0826.

**(h) Subject**

Joint Aircraft Service Component (JASC) Code: 7100, Powerplant System.

Issued in Fort Worth, Texas, on September 17, 2013.

**Gwendolynne O'Connell,**

*Acting Directorate Manager, Rotorcraft Directorate, Aircraft Certification Service.*

[FR Doc. 2013–23437 Filed 9–25–13; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Food and Drug Administration

## 21 CFR Part 514

**[Docket No. FDA–2012–N–0447]**

## Antimicrobial Animal Drug Sales and Distribution Annual Summary Report Data Tables

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

**ACTION:** Notification; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA) is seeking comment on a proposal regarding the content and format of data tables for the Agency's annual summary report of sales and distribution data collected from sponsors of antimicrobial new animal drugs in accordance with the new animal drug records and reporting provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended by the Animal Drug User Fee Amendments of 2008 (ADUFA).

**DATES:** Submit electronic or written comments by November 25, 2013.

**ADDRESSES:** Submit electronic comments on this proposal to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 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, email: *Neal.Bataller@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

Section 512(*l*) of the FD&C Act (21 U.S.C. 360b(*l*)) 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. Section 105 of ADUFA (Pub. L. 110–316) directed the Agency to collect data and information about antimicrobial new animal drugs approved for use in food-producing animals by amending section 512(*l*) of the FD&C Act to include new reporting requirements for sponsors of these drugs. Under new section 512(*l*)(3) of the FD&C Act, antimicrobial new animal drug sponsors are required to submit to FDA on an annual basis a report specifying the amount of each antimicrobial active ingredient sold or distributed for each of the sponsor's drug products that are approved 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 by 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 sponsors of antimicrobial new animal drugs approved for use in food-producing animals, and further provides that such data must be reported by antimicrobial class. Section 512(*l*)(3)(E) of the FD&C Act directs FDA not to independently report those antimicrobial classes with fewer than three distinct sponsors and further directs FDA to report the data in a manner consistent with protecting both national security and confidential business information.

In the **Federal Register** of July 27, 2012 (77 FR 44177), FDA published an advanced notice of proposed rulemaking (ANPRM) to seek public comment on, among other things, additional ways in which the FDA could compile and present this summary information that are useful to the public while maintaining confidential business information. The proposed additional data tables for the Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals presented in this notice were developed in response to the comments FDA received.

## II. Proposed Additional Data Tables for the Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals

Consistent with section 512(*l*)(3) of the FD&C Act, FDA's current format for its annual summary report only includes gross antimicrobial drug sales and distribution data by antimicrobial drug class without further subdivision. This format is illustrated in Table 1 with supporting Table 2. FDA proposes to retain these tables in future summary reports. However, many of the comments we received in response to the July 27, 2012, ANPRM suggested that alternative summaries of the antimicrobial drug sales and distribution data are needed by the scientific community and public interest groups to enhance their understanding of antimicrobial resistance. Such suggestions commonly included further reporting by importance to human medicine, route of drug administration, dispensing status, or indications. In response to these suggestions, FDA proposes to add four additional data tables to its annual summary report as illustrated by Tables 3 through 6. FDA is seeking comment on this proposal.

FDA believes that summarizing domestic sales and distribution data for antimicrobial new animal drugs approved for use in food-producing animals using the four additional formats (outlined in Tables 3 through 6) is currently possible without revealing the confidential business information of any one new animal drug sponsor. These additional tables summarize the domestic sales and distribution information received by FDA by first aggregating the data based on human medical importance [1] and then further breaking down the data by antimicrobial drug class, route of administration, dispensing status, and indications. Export sales and distribution data are not included in the proposed additional tables due to the limited number of categories that could be independently reported.

This approach makes it possible to present domestic sales and distribution data in a manner that does not violate the confidentiality provisions of section 512(*l*) of the FD&C Act. While the ''no class with fewer than 3 distinct sponsors'' requirement of section 512(*l*)(3)(E)(i) of the FD&C Act specifically applies to summary reporting by antimicrobial drug class, FDA notes that it is also obligated to comply with the more broadly written requirement of section 512(*l*)(3)(E)(ii) of the FD&C Act that such ''data shall be reported in a manner consistent with protecting . . . confidential business information.'' [2] In order to ensure that we are in compliance with these requirements, FDA has interpreted these provisions to mean that our annual data summary must: (1) Only report data for a given drug class (or any other data category) for which there are at least three distinct sponsors and (2) otherwise be consistent with protecting confidential business information.

Based on our analysis of currently available information, FDA believes that all data categories in the proposed additional tables (e.g., sales reported by medical importance and indication) would consist of combined sales and distribution data from at least three sponsors. For example, in Table 5, there are only two sponsors of medically important antimicrobial animal drug products approved solely for production indications (i.e., have no therapeutic indications); therefore, reporting this data point would reveal each sponsor's sales and distribution data to the other. In order to protect confidential business information, this category has been combined with antimicrobial animal drugs approved for both production and therapeutic indications.

In evaluating possible approaches to categorizing data in the proposed additional tables, FDA also took into account whether particular data points could be utilized to indirectly derive other data points that would reveal confidential business information. FDA believes the broad requirement to protect confidential business information means the Agency cannot independently report data if it can be used together with data presented elsewhere or data already in the public domain to derive confidential business

[1] Draft Guidance for Industry #213 proposes that all antimicrobial drugs and their associated classes listed in Appendix A to FDA's Guidance for Industry #152 (Appendix A) be considered ''medically important.''

[2] 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.

information. The concept that a piece of information that, in and of itself would not cause substantial competitive harm if released, would likely cause substantial competitive harm if released in light of other publicly available information, often referred to as the ''mosaic'' effect, has been recognized by the Courts as a legitimate issue of concern in the context of protecting confidential business information.[3]

After considering various approaches, FDA is proposing as a first level of categorization in the new tables to distinguish between those antimicrobial drug products that are important for human medicine and those that are not important for human medicine. Stakeholder comments to the July 2012 ANPRM docket support this presentation. In addition, this approach highlights the public health relevance of these data, and is consistent with the FDA's strategy to promote the judicious use of medically important antimicrobials used in food-producing animals. FDA also proposes, as a second level of categorization, to further break down the aggregated medical importance data by antimicrobial drug class, route of administration, indications, and dispensing status.

FDA considered a third level of categorization for Tables 4–6, beyond breaking down the aggregated medical importance data by route of administration, indications, and dispensing status, to present such sales and distribution data by individual drug class. However, after analysis FDA found that summarizing sales and distribution data for antimicrobial new animal drugs approved for use in food-producing animals in this manner posed concerns related to disclosure of confidential business information, either by revealing data representing fewer than three sponsors or providing sufficient information to allow indirect calculation of confidential business information. If such data points were to be disclosed, this would be inconsistent with the confidentiality provisions of section 512(*l*)(3)(E) of the FD&C Act. Alternatively, redacting or comingling these data points would frequently result in summary tables comprised primarily of data collated into a single ''not independently reported'' (NIR) category.

Therefore, the Agency believes the additional data tables proposed for inclusion in the ''Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals'' would provide a more useful summary report without violating the confidentiality provisions of section 512(*l*) of the FD&C Act. The new proposed data tables (described in section II.B.) are intended to augment the data tables provided in previous Summary Reports (described in section II.A.). FDA acknowledges that, based on changes that may occur in the animal drug industry, in the future we may further reformat the data tables as necessary to protect confidential business information or, if possible, to present the data in a more detailed manner. However, based on an analysis of the products marketed at this time, FDA believes the data tables presented in this proposal provide the most feasible approach for including an enhanced level of detail in the annual summary reports while still maintaining adequate protection for confidential business information.

*A. Existing Data Table Formats*

FDA has included the following tables in previous Summary Reports and proposes to continue including these types of data summaries in future reports.

1. Sales and Distribution Data Reported by Drug Class

Table 1 presents data on annual domestic and export sales and distribution of antimicrobial active ingredients approved for use in food-producing animals, broken down by antimicrobial drug class.

TABLE 1—ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS: SALES AND DISTRIBUTION DATA REPORTED BY ANTIMICROBIAL CLASS MARKETED IN 20XX

| | Antimicrobial Class | Annual Totals (kg[1]) |
|---|---|---|
| Domestic | Antimicrobial Class 1 | |
| | Antimicrobial Class 2[2] | |
| | Antimicrobial Class 3, Etc.* | |
| | NIR[3] | |
| Export[4] | Antimicrobial Class 1 | |
| | Antimicrobial Class 2[2] | |
| | Antimicrobial Class 3, Etc.* | |
| | NIRE[5] | |

[1] kg = kilogram of active ingredient. Antimicrobials which were reported in International Units (IU) (e.g., Penicillins) were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

[2] Includes antimicrobial drug products which are approved and labeled for use in multiple species, including both food- and nonfood-producing animals, such as dogs and cats.

[3] NIR = Not Independently Reported. Antimicrobial classes for which fewer than three distinct sponsors actively marketed products domestically were not independently reported. These classes include: [list of drug classes].

[4] Only includes exports of FDA-approved, U.S.-labeled antimicrobial drugs approved for use in food-producing animals.

[5] NIRE = Not Independently Reported Export. Antimicrobial classes for which fewer than three distinct sponsors exported products were not independently reported. These classes include: [list of drug classes].

* Drug classes independently reported are based on number of distinct sponsors marketing drug products in each class during the calendar year.

[3] See e.g., *Timken Company* v. *United States Customs Service,* 491 F. Supp. 557, 559 (D.D.C. 1980) (court held that disclosure of data furnished by importer of Japanese roller bearings would cause substantial competitive harm to both the importer and the exporter by allowing competitors and customers to indirectly calculate the company's profit margin and production costs, thereby giving competitors insight into the company's ''competitive strengths and weaknesses''); *Customs & International Trade Newsletter* v. U.*S. Customs and Border Protection,* 588 F. Supp. 2d 51, 57 (D.D.C. 2008) (names and addresses of certain importers were properly withheld by the government because that information, ''when cross-referenced with publicly available . . . information . . . would reveal information that could cause substantial competitive harm.'').

*2. Marketed Antimicrobial Drugs and Drug Classes Approved for Use in Food-Producing Animals*

Table 2 lists all antimicrobial active ingredients approved for use in food-producing animals broken down by antimicrobial drug classes that were actively marketed during the specific calendar year for which sales and distribution data were reported.

TABLE 2—ANTIMICROBIAL DRUG CLASSES AND ACTIVE INGREDIENTS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS * MARKETED IN 20XX

| Antimicrobial Class 1 | Antimicrobial Class 2, Etc.*** |
|---|---|
| Active Ingredient A | Active Ingredient A. |
| Active Ingredient B | Active Ingredient B. |
| Active Ingredient C, Etc.** | Active Ingredient C, Etc.** |

* Includes some antimicrobial drug products which are approved and labeled for use in multiple species, including both food- and nonfood-producing animals, such as dogs and cats.
** Active ingredients reported are based on drug products actively marketed during the calendar year.
*** Antimicrobial classes reported are based on drug products actively marketed in each class during the calendar year.

**B. Proposed Additional Tables**

Comments received in response to the July 27, 2012, ANPRM (77 FR 44177) commonly included suggestions for further reporting of antimicrobial classes by route of drug administration, dispensing status, or indications, and differentiation between drug classes of human medical importance and those not important to human medicine. Based on the comments received in response to the 2012 ANPRM, FDA has developed four additional proposed tables for inclusion in its annual Summary Report. In developing these new tables, FDA initially attempted to further break down the data for individual drug classes by route of administration, dispensing status, and indications, but found that very few classes could be independently reported in a manner consistent with protecting confidential business information. Therefore, FDA determined that reporting the data instead by medical importance with further divisions by drug class (Table 3); route of administration (Table 4); indications (Table 5); and dispensing status (Table 6) would present more meaningful information while continuing to protect confidential business information. Export data were not included in the proposed additional tables due to the limited number of categories that could be independently reported. FDA proposes to include these additional tables in future reports and to update previously published annual summaries to include similar data tables.

*1. Domestic Sales and Distribution Data Reported by Medical Importance and Drug Class*

Table 3 presents data on annual domestic sales and distribution of antimicrobial active ingredients approved for use in food-producing animals broken down by human medical importance and antimicrobial drug class.

TABLE 3—ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS: * DOMESTIC SALES AND DISTRIBUTION DATA REPORTED BY MEDICAL IMPORTANCE AND DRUG CLASS MARKETED IN 20XX

| | Annual totals (kg) [1] |
|---|---|
| Medically Important: [2] | |
| Antimicrobial Class 1 | |
| Antimicrobial Class 2 | |
| Antimicrobial Class 3, Etc.** | |
| NIR [3] | |
| Not Medically Important: [4] | |
| Antimicrobial Class 1 | |
| Antimicrobial Class 2 | |
| Antimicrobial Class 3, Etc.** | |
| NIR [5] | |

[1] kg = kilogram of active ingredient. Antimicrobials which were reported in International Units (IU) (e.g., Penicillins) were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

[2] Draft Guidance for Industry #213 proposes that all antimicrobial drugs and their associated classes listed in Appendix A to FDA's Guidance for Industry #152 (Appendix A) be considered ''medically important.''

[3] NIR = Not Independently Reported. Medically Important antimicrobial classes for which there were less than three distinct sponsors actively marketing products domestically were not independently reported. These classes include: [list of drug classes].

[4] ''Not Medically Important'' refers to any antimicrobial class *not* currently listed in Appendix A.

[5] NIR = Not Independently Reported. Not Medically Important antimicrobial classes for which there were less than three distinct sponsors actively marketing products domestically were not independently reported. These classes include: [list of drug classes].

* Includes some antimicrobial drug products which are approved and labeled for use in multiple species, including both food- and nonfood-producing animals, such as dogs and cats.

** The total number of antimicrobial classes independently reported depends upon the number of distinct sponsors marketing drug products in each class during the calendar year. Only those antimicrobial classes with 3 or more distinct sponsors will be reported independently.

*2. Domestic Sales and Distribution Data Reported by Medical Importance and Route of Administration*

Table 4 presents data on annual domestic sales and distribution of antimicrobial active ingredients approved for use in food-producing animals broken down by medical importance and route of administration.

TABLE 4—ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS: * DOMESTIC SALES AND DISTRIBUTION DATA REPORTED BY MEDICAL IMPORTANCE AND ROUTE OF ADMINISTRATION MARKETED IN 20XX

| | Annual totals (kg) [1] |
|---|---|
| Medically Important: | |
| Feed | |
| Water | |
| Injection | |
| Other Routes [2] | |
| Not Medically Important: | |
| Feed | |
| Water | |
| Injection | |
| Other Routes [2] | |

[1] kg = kilogram of active ingredient. Antimicrobials which were reported in International Units (IU) (e.g., Penicillins) were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

[2] The Other Routes category includes the following: Water/Topical Immersion for Fish, Water/Drench, Intramammary, Oral, and Topical.

* Includes some antimicrobial drug products which are approved and labeled for use in multiple species, including both food- and nonfood-producing animals, such as dogs and cats.

*3. Domestic Sales and Distribution Data Reported by Medical Importance and Indications*

Table 5 presents data on annual domestic sales and distribution of antimicrobial active ingredients approved for use in food-producing animals broken down by medical importance and indications. Antimicrobials are approved for two basic categories of indications in food-producing animals: Therapeutic (treatment, control, or prevention of a specific bacterial disease), and production (increased rate of weight gain or improved feed efficiency). While 512(*l*)(3) of the FD&C Act requires that sponsors report a listing of indications that are specified on the approved label of the product, sponsors currently are not required to report sales and distribution data broken down by individual indications. Most products are approved for more than one indication; therefore, FDA is unable to report sales and distribution data for specific active ingredients broken down by individual indications. Very few products are approved solely for production indications; therefore this category could not be independently reported. Many, however, are approved solely for therapeutic indications, or for a combination of therapeutic and production indications. As a result, it is possible to present sales and distribution data for products approved solely for therapeutic indications, and products approved for both production and therapeutic indications, but not for the few products approved solely for production indications (see Table 5, footnote 4). It is important to note that this latter category does not represent the quantity actually used for production purposes, since the vast majority of antimicrobials in this category also have therapeutic claims.

TABLE 5—ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS: * DOMESTIC SALES AND DISTRIBUTION DATA REPORTED BY MEDICAL IMPORTANCE AND INDICATIONS MARKETED IN 20XX

| | Annual totals (kg) [1] |
|---|---|
| Medically Important: | |
| Therapeutic [2] Indications Only | |
| Production [3] and Therapeutic Indications [4] | |
| Not Medically Important: | |
| Therapeutic Indications Only | |
| Production and Therapeutic Indications [4] | |

[1] kg = kilogram of active ingredient. Antimicrobials which were reported in International Units (IU) (e.g., Penicillins) were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

[2] Therapeutic Indications = treatment, control, or prevention of a specific bacterial disease.

[3] Production Indications = ''increased rate of weight gain'' or ''improved feed efficiency.''

[4] In both the Medically Important and the Not Medically Important categories, there are currently fewer than three distinct sponsors marketing antimicrobial animal drug products approved solely for production indications (no therapeutic indications). To protect confidential business information these data cannot be independently reported and have, therefore, been included with drugs approved for both production and therapeutic indications.

* Includes some antimicrobial drug products which are approved and labeled for use in multiple species, including both food- and nonfood-producing animals, such as dogs and cats.

*4. Domestic Sales and Distribution Data Reported by Medical Importance and Dispensing Status*

Table 6 presents data on annual domestic sales and distribution of antimicrobial active ingredients approved for use in food-producing animals broken down by medical importance and dispensing status (i.e., whether the product is sold over-the-counter or requires veterinary oversight). Medicated feeds requiring veterinary oversight are designated ''veterinary feed directive'' (VFD) status; all other new animal drug products requiring veterinary oversight are designated ''prescription'' status. This table combines products requiring veterinary oversight because the VFD category currently only includes three ''medically important'' products marketed by two distinct sponsors; therefore reporting the VFD category independently would not be in a manner consistent with the protection of confidential business information. If the prescription and VFD categories are able to be reported independently at a later date, the table will reflect this.

TABLE 6—ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS: * DOMESTIC SALES AND DISTRIBUTION DATA REPORTED BY MEDICAL IMPORTANCE AND DISPENSING STATUS MARKETED IN 20XX

| | Annual totals (kg) [1] |
|---|---|
| Medically Important: | |
| OTC [2] | |
| Rx [3] or VFD [4 5] | |
| Not Medically Important: | |
| OTC | |
| Rx | |

[1] kg = kilogram of active ingredient. Antimicrobials which were reported in International Units (IU) (e.g., Penicillins) were converted to kg. Antimicrobial class includes drugs of different molecular weights, with some drugs reported in different salt forms.

[2] OTC = Over-The-Counter veterinary drug products. Such products are available without a prescription or veterinary feed directive.

[3] Rx = prescription veterinary drug products. Such products require a prescription from a licensed veterinarian.

[4] VFD = Veterinary Feed Directive drug products. Such products are intended for use in or on animal feed and must be used under the professional supervision or oversight of a veterinarian.

[5] The ''Rx or VFD'' category includes three medically important VFD products marketed by two distinct sponsors and, therefore, cannot be independently reported. There are no VFD products in the Not Medically Important category.

* Includes some antimicrobial drug products which are approved and labeled for use in multiple species, including both food- and nonfood-producing animals, such as dogs and cats.

## III. 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.*

Dated: September 23, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–23488 Filed 9–25–13; 8:45 am]

**BILLING CODE 4160–01–P**