TABLE 1—ANDAS FOR WHICH FDA IS WITHDRAWING APPROVAL—Continued

Application No.	Drug	Applicant
ANDA 075375	Diltiazem Hydrochloride (HCl) Injection, 5 mg/milliliter (mL)	Mylan Laboratories, Ltd., c/o Mylan Pharmaceuticals, Inc., 781 Chestnut Ridge Rd., P.O. Box 4310, Morgantown, WV 26504.
ANDA 076911	Clorazepate Dipotassium Tablets USP, 3.75 mg, 7.5 mg, and 15 mg.	Sun Pharmaceutical Industries, Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 077102	Calcitriol Injection, 0.001 mg/mL	Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd., Suite 450, Schaumburg, IL 60195.
ANDA 084656	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Roxane Laboratories, Inc., 1809 Wilson Rd., Columbus, OH 43228.
ANDA 087977	Diphenhydramine HCl Capsules, 25 mg	LNK International, Inc., 145 Ricefield Ln., Hauppauge, NY 11788.
ANDA 088676	Methylprednisolone Sodium Succinate for Injection USP, Equivalent to 40 mg base/vial.	LyphoMed, Division of Fujisawa USA, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160.
ANDA 089080	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Purepac Pharmaceutical Co., 200 Elmora Ave., Elizabeth, NJ 07207.
ANDA 089183	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg.	Superpharm Corp., 1769 Fifth Ave., Bayshore, NY 11706.
ANDA 089253	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Do.
ANDA 089219	Procainamide HCl Capsules USP, 250 mg, 375 mg, and 500 mg.	IDT Australia, Ltd., c/o Facet Life Sciences, Inc., 6122 Stone Wolfe Dr., Glen Carbon, IL 62034.
ANDA 089254	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Do.
ANDA 089369	Procainamide HCl Extended-Release Tablets USP, 250 mg, 500 mg, and 750 mg.	Do.
ANDA 089481	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/15 mg.	American Therapeutics, Inc., 75 Carlough Rd., Bohemia, NY 11716.
ANDA 089482	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/30 mg.	Do.
ANDA 089483	Acetaminophen and Codeine Phosphate Tablets USP, 300 mg/60 mg.	Do.
ANDA 206711	Olanzapine Tablets USP, 2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg, and 20 mg.	Ajanta Pharma, Ltd., c/o Ajanta Pharma USA, Inc., One Grande Commons, 440 U.S. Highway 22 East, Suite 150, Bridgewater, NJ 08807.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn as of February 16, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in table 1 that are in inventory on the date that this notice becomes effective (see the **DATES** section) may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00695 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0155]

Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of our veterinary feed directive (VFD) regulation.

DATES: Submit either electronic or written comments on the collection of information by March 19, 2018.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 19, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 19, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to

the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

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

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2010–N–0155 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Veterinary Feed Directive.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–7726, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following 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.

Veterinary Feed Directive—21 CFR 558.6

OMB Control Number 0910–0363—Extension

Section 504 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 354) establishes a regulatory category for certain new animal drugs called VFD drugs. Our VFD regulation is set forth at § 558.6 (21 CFR 558.6). VFD drugs are new animal drugs intended for use in or on animal feed which are limited to use under the professional supervision of a licensed veterinarian in the course of the veterinarian's professional practice (§ 558.3 (21 CFR 558.3(b)(6))). An animal feed containing a VFD drug or a combination VFD drug may be fed to animals only by or upon a lawful VFD issued by a licensed veterinarian (§ 558.6(a)(1)).

Veterinarians issue three copies of the VFD: one for their own records, one for their client, and one to the client's VFD feed distributor (§§ 558.6(a)(4) and 558.6(b)(8)–(9)). The VFD includes information about the number and species of animals to receive feed containing one or more of the VFD drugs (§ 558.6(b)(3)), along with other information required under § 558.6. All distributors of medicated feed containing VFD drugs must notify us of their intent to distribute such feed and must maintain records of the receipt and distribution of all medicated feeds containing VFD drugs.

The VFD regulation ensures the protection of public health while enabling animal producers to obtain and use needed drugs as efficiently and cost-effectively as possible. The VFD regulation is tailored to the unique circumstances relating to the distribution and use of animal feeds containing a VFD drug.

We will use the information collected to assess compliance with the VFD regulation. The required recordkeeping and third party disclosures provide assurance that the medicated feeds will be safe and effective for their labeled conditions of use and that edible

products from treated animals will be free of unsafe drug residues.

We estimate the burden of this collection of information as follows. We base our estimates on our analysis of the information collection provisions of the final rule entitled ''Veterinary Feed Directive,'' published in the **Federal Register** of June 3, 2015 (80 FR 31708 at 31728) (the June 3, 2015, final rule).

A. Reporting Requirements

Description of Respondents: VFD Feed Distributors, VFD Drug Sponsors.

A distributor of animal feed containing a VFD drug must notify us prior to the first time it distributes the VFD feed (§ 558.6(c)(5)). This notification is required one time per distributor and must include the information set forth in § 558.6(c)(5). In addition, a distributor must notify us within 30 days of any change in ownership, business name, or business address (§ 558.6(c)(6)). Additional reporting burdens for current VFD drug sponsors are approved under OMB control numbers 0910–0032 (New Animal Drug Applications) and 0910–0669 (Abbreviated New Animal Drug Applications).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section, activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
558.6(c)(5); requires a distributor to notify us prior to the first time it distributes a VFD feed.	300	1	300	.125 (7 minutes)	37.5
558.6(c)(6); requires a distributor to notify us within 30 days of any change in ownership, business name, or business address.	20	1	20	.125 (7 minutes)	2.5
Total					40

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

B. Recordkeeping Requirements

Description of Respondents: VFD Feed Distributors, Food Animal Veterinarians, and Clients (Food Animal Producers).

As stated previously, veterinarians issue three copies of the VFD: One for their own records, one for their client, and one to the client's VFD feed distributor. All involved parties (the veterinarian, the distributor, and the client) must retain a copy of the VFD for 2 years (§ 558.6(a)(4)). In addition, VFD feed distributors must also keep receipt and distribution records of VFD feeds they manufacture and make them available for inspection by us for 2 years (§ 558.6(c)(3)).

If a distributor manufactures the VFD feed, the distributor must also keep VFD manufacturing records for 1 year in accordance with 21 CFR part 225 and such records must be made available for inspection and copying by FDA upon request (§ 558.6(c)(4)). These record requirements are currently approved under OMB control number 0910–0152, ''Current Good Manufacturing Practice Regulations for Medicated Feed.'' Distributors may distribute VFD to another distributor only if the originating distributor first obtains a written acknowledgement letter. Such letters, like VFDs, are also subject to a 2-year record retention requirement (§ 558.6(c)(8)).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section, activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
558.6(a)(4); required recordkeeping by veterinarians and producers.	13,050	114.9	1,500,000	.0167 (1 minute)	25,050
558.6(a)(4), (c)(3)–(4), and (c)(8); required recordkeeping by distributors.	1,376	545.1	750,000	.0167 (1 minute)	12,525
Total					37,575

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

C. Third-Party Disclosure Requirements

Description of Respondents: VFD Drug Sponsors, Food Animal Veterinarians, VFD Feed Distributors, and Clients.

Our regulation requires that veterinarians include the information specified at § 558.6(b)(3) through (5) on the VFD. Additional requirements relating to the VFD are specified at § 558.6(b)(7) through (9). A distributor may only distribute a VFD feed to another distributor for further distribution if the originating distributor (consignor) first obtains a written acknowledgement letter from the receiving distributor (consignee) before the feed is shipped (§ 558.6(c)(8)).

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section, activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
558.6(b)(3)–(5) and (b)(7)-(9); required disclosures when a veterinarian issues a VFD.	3,050	246	750,000	.125 (7 minutes)	93,750
558.6(c)(8); required disclosure (acknowledgement letter) from one distributor to another.	1,000	5	5,000	.125 (7 minutes)	625
Total					94,375

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

The VFD regulation also contains several labeling provisions that are exempt from OMB review and approval under the PRA because they are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501, *et seq.*). All labeling and advertising for VFD drugs, combination VFD drugs, and feeds containing VFD drugs or combination VFD drugs must prominently and conspicuously display the following cautionary statement: ''Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian'' (§ 558.6(a)(6)). In addition, the veterinarian must ensure that the following statement is included on the VFD (§ 558.6(b)(3)(xiii)): ''Use of feed containing this veterinary feed directive (VFD) drug in a manner other than as directed on the labeling (extralabel use) is not permitted.''

The veterinarian may restrict VFD authorization to only include the VFD drug(s) cited on the VFD or such authorization may be expanded to allow the use of the cited VFD drug(s) along with one or more over-the-counter animal drugs in an approved, conditionally approved, or indexed combination VFD drug (§ 558.6(b)(6)). The veterinarian must affirm his or her intent regarding combination VFD drugs by including one of the following statements on the VFD:

1. ''This VFD only authorizes the use of the VFD drug(s) cited in this order and is not intended to authorize the use of such drug(s) in combination with any other animal drugs'' (§ 558.6(b)(6)(i)).

2. ''This VFD authorizes the use of the VFD drug(s) cited in this order in the following FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component.'' (List specific approved, conditionally approved, or indexed combination medicated feeds following this statement. § 558.6(b)(6)(ii).)

3. ''This VFD authorizes the use of the VFD drug(s) cited in this order in any FDA-approved, conditionally approved, or indexed combination(s) in medicated feed that contains the VFD drug(s) as a component'' (§ 558.6(b)(6)(iii)).

These labeling statements are not subject to review by OMB because, as stated previously, they are a ''public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)) and therefore do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501, *et seq.*). Our estimate of the annual burden for this information collection has not changed since the last OMB approval, which was associated with the June 3, 2015, final rule. However, the one-time burdens that we included in our analysis of the June 3, 2015, final rule (80 FR 31708 at 31729 to 31732) are not included in our current estimate.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00676 Filed 1–16–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–E–3619]

Determination of Regulatory Review Period for Purposes of Patent Extension; AXUMIN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for AXUMIN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by March 19, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 16, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 19, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of March 19, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

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- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://*