actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product DAKLINZA (daclatasvir dihydrochloride). DAKLINZA is indicated for use with sofosbuvir for the treatment of chronic HCV genotype 3 infection. Subsequent to this approval, the USPTO received a patent term restoration application for DAKLINZA (U.S. Patent No. 8,329,159) from Bristol-Myers Squibb Company, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated July 12, 2016, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of DAKLINZA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for DAKLINZA is 2,808 days. Of this time, 2,327 days occurred during the testing phase of the regulatory review period, while 481 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* November 17, 2007. The applicant claims November 16, 2007, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was November 17, 2007, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* March 31, 2014. FDA has verified the applicant's claim that the new drug application (NDA) for DAKLINZA (NDA 206843) was initially submitted on March 31, 2014.

3. *The date the application was approved:* July 24, 2015. FDA has verified the applicant's claim that NDA 206843 was approved on July 24, 2015.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 467 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: January 11, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–00675 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–2017–N–0002]

Delcor Asset Corp. et al.; Withdrawal of Approval of 22 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 22 abbreviated new drug applications (ANDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of February 16, 2018.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945, *Trang.Tran@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1—ANDAS FOR WHICH FDA IS WITHDRAWING APPROVAL

Application No.	Drug	Applicant
ANDA 060577	Mycostatin (nystatin) Vaginal Tablets, 100,000 units	Delcor Asset Corp., 411 South State St., Suite E–100, Newtown, PA 18940.
ANDA 063302	Cefamandole Nafate for Injection	ACS Dobfar SpA, c/o Interchem Corp., 120 Route 17 North, Paramus, NJ 07653.
ANDA 070462	Diazepam Tablets USP, 2 milligrams (mg)	Virtus Pharmaceuticals, 12 Penns Trail, Newtown, PA 18940.
ANDA 070463	Diazepam Tablets USP, 5 mg	Do.
ANDA 070998	Potassium Chloride Extended-Release Tablets, 8 milli-equivalents (mEq).	Future Pak, Ltd., 28115 Lakeview Dr., Wixom, MI 48393.
ANDA 070999	Potassium Chloride Extended-Release Tablets, 10 mEq	Do.

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