1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: June 21, 1998. The applicant claims June 19, 1998, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 21, 1998, 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 act*: September 8, 2003. The applicant claims September 5, 2003, as the date the new drug application (NDA) for SENSIPAR (NDA 21–688) was initially submitted. However, FDA records indicate that NDA 21–688 was submitted on September 8, 2003, which is considered to be the initially submitted date.

3. *The date the application was approved*: March 8, 2004. FDA has verified the applicant's claim that NDA 21–688 was approved on March 8, 2004.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 449 days of patent term extension for U.S. Patent Nos. 6,011,068 and 6,313,146, and 627 days of patent term extension for U.S. Patent No. 6,211,244.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by July 13, 2009. 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 November 10, 2009. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (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.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 6, 2009.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research

[FR Doc. E9–11219 Filed 5–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0188]

Determination That DECADRON Tablets and Nine Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that the 10 drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Olivia Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6308, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved; (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved; and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for reasons of safety or effectiveness, the agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table in this document are no longer being marketed. (As requested by the applicant, FDA withdrew approval of NDA 18–821 for REGLAN (metoclopramide) Oral Solution in the **Federal Register** of October 10, 2002 (67 FR 63107).)

Application No.	Drug	Applicant
NDA 11–664	DECADRON (dexamethasone) Tablets, 0.5 milligram (mg) and 0.75 mg	Merck & Co., P.O. Box 4, BLA–20, West Point, PA 19486
NDA 15–229	AMICAR (aminocaproic acid) Injection, 250 mg/milliliter (mL)	Xanodyne Pharmaceuticals, Inc., One Riverfront Pl., Newport, KY 41071–4563

Application No.	Drug	Applicant
NDA 16–636	NARCAN (naloxone hydrocholoride (HCl)) Injection, 0.02 mg/mL, 0.4 mg/mL, and 1 mg/mL	Endo Pharmaceuticals, Inc., 100 Painters Dr., Chadds Ford, PA 19317
NDA 16–929	FUDR (floxuridine) Injection, 500 mg/vial	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045
NDA 18–538	LOZOL (indapamide) Tablets, 1.25 mg and 2.5 mg	Sanofi-Aventis U.S., 55 Corporate Blvd., P.O. Box 5925, Bridgewater, NJ 08807
NDA 18–821	REGLAN (metaclopramide HCl) Oral Solution, equivalent to (EQ) 5 mg base/5 mL	A.H. Robins Co., c/o Wyeth-Ayerst Research, P.O. Box 8299, Philadelphia, PA 19101–8299
NDA 18–831	TRACRIUM (atracurium besylate) Injection, 10 mg/mL	Hospira, Inc.
NDA 18–831	TRACRIUM (atracurium besylate) Preservative Free Injection, 10 mg/mL	Do.
NDA 19–080	PROSOM (estazolam) Tablets, 1 mg and 2 mg	Abbott Laboratories, 200 Abbott Park Rd., D–491, AP30–1E, Abbott Park, IL 60064–6157
NDA 20–397	ZANAFLEX (tizanidine HCL) Tablets, EQ 2 mg base	Acorda Therapeutics, 15 Skyline Dr., Hawthorne, NY 10532

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list the drug products listed in this document in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed in this document are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the agency will advise ANDA applicants to submit such labeling.

Dated: May 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–11217 Filed 5–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0189]

Guidance for Industry: Animal Generic Drug User Fees and Fee Waivers and Reductions; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document for industry (#199) entitled ''Animal Generic Drug User Fees and Fee Waivers and Reductions.'' The purpose of this document is to provide guidance to industry on the Animal Generic Drug User Fee Act of 2008 (AGDUFA). FDA is issuing this final guidance document for immediate implementation consistent with the agency's good guidance practices (GGPs). Interested persons may submit comments on agency guidances at any time.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the guidance document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: David Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8307, e-mail: *dnewkirk@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

On August 14, 2008, AGDUFA (Public Law 110–316) was enacted. AGDUFA amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and requires FDA to assess and collect user fees for certain applications, products, and sponsors. It also requires the agency to grant a waiver from or a reduction of fees in certain circumstances. Under section 741(d) of the FD&C Act, when certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication.

The purpose of the guidance document is to provide guidance on the types of fees FDA is authorized to collect under AGDUFA and how to request waivers and reductions of these fees. It describes the types of fees, the type of fee waiver or reduction