

“000409, 054771, and 068330” and in its place add “054771 and 068330”.

■ 14. In § 522.2075, revise paragraph (c) to read as follows:

§ 522.2075 Robenacoxib.

* * * * *

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount*. Administer 0.91 mg per pound (2 mg/kilogram (kg)) by subcutaneous injection, once daily, for a maximum of 3 days. After the initial subcutaneous dose, subsequent doses can be given by subcutaneous injection or as the oral tablet in dogs weighing at least 5.5 pounds (2.5 kg) and at least 4 months of age, for a maximum of 3 total doses over 3 days, not to exceed 1 dose per day. See § 520.2075(c)(1) of this chapter.

(ii) *Indications for use*. For the control of postoperative pain and inflammation associated with soft tissue surgery in

dogs at least 4 months of age for a maximum of 3 days.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) *Cats*—(i) *Amount*. Administer 0.91 mg per pound (2 mg/kg) by subcutaneous injection, once daily, for a maximum of 3 days.

(ii) *Indications for use*. For the control of postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy, and castration in cats at least 4 months of age for a maximum of 3 days.

(iii) *Limitations*. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 15. The authority citation for part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.1186 [Amended]

■ 16. Effective March 13, 2017, in § 529.1186, in paragraph (b), remove “010019,”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 17. The authority citation for part 558 continues to read as follows:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 18. In § 558.325, revise paragraph (e)(1)(ii) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(e) * * *

(1) * * *

Lincomycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 2	Halofuginone 2.72	Broiler chickens: For the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to lincomycin; and the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .	Feed continuously as sole ration. Withdraw 4 days before slaughter. Do not feed to laying chickens or waterfowl. Halofuginone hydrobromide as provided by No. 016592 in §510.600 of this chapter.	016592

* * * * *

Dated: February 23, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–03930 Filed 2–28–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 529

[Docket No. FDA–2017–N–0002]

New Animal Drugs; Withdrawal of Approval of a New Animal Drug Application

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of a new animal drug application (NADA) and an abbreviated

new animal drug application (ANADA) at the sponsors’ requests because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective March 13, 2017.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, sujaya.dessai@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The sponsors of the following applications have requested that FDA withdraw approval of the NADA and ANADA listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product name	21 CFR section
135–773	Baxter Healthcare Corp., One Baxter Pkwy., Deerfield, IL 60015.	AERRANE (isoflurane USP)	529.1186
200–421	Hospira, Inc., 275 North Field Dr., Lake Forest, IL 60045.	Ceftiofur (ceftiofur Na) for Injection	522.313c

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 135-773 and ANADA 200-421, and all supplements and amendments thereto, is hereby withdrawn, effective March 13, 2017.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: February 23, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-03931 Filed 2-28-17; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA-2016-N-4661]

Gastroenterology-Urology Devices; Manual Gastroenterology-Urology Surgical Instruments and Accessories

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the identification of manual gastroenterology-urology surgical instruments and accessories to reflect that the device does not include specialized surgical instrumentation for use with urogynecologic surgical mesh specifically intended for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures (“specialized surgical instrumentation for use with urogynecologic surgical mesh”). These amendments are being made to reflect changes made in the recently issued final reclassification order for specialized surgical instrumentation for use with urogynecologic surgical mesh.

DATES: This rule is effective March 1, 2017.

FOR FURTHER INFORMATION CONTACT:

Sharon Andrews, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. G110, Silver Spring, MD 20993, 301-796-6529, Sharon.Andrews@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: FDA is amending § 876.4730 (21 CFR 876.4730, Manual gastroenterology-urology surgical instrument and accessories), by adding language to the identification of the device to reflect that specialized surgical instrumentation for use with urogynecologic surgical mesh is no longer regulated under § 876.4730.

In the **Federal Register** of November 23, 1983 (48 FR 53012), FDA issued a final rule classifying manual gastroenterology-urology surgical instrument and accessories into class I under § 876.4730 (48 FR 53012 at 53025). Certain specialized surgical instrumentation for use with urogynecologic surgical mesh was regulated as class I devices under that regulation. In the **Federal Register** of January 6, 2017 (82 FR 1598), FDA issued a final order reclassifying specialized surgical instrumentation for use with urogynecologic surgical mesh from class I (general controls) exempt from premarket notification to class II (special controls) and subject to premarket notification. As a result of that final reclassification order, FDA is amending the identification at § 876.4730(a) to reflect that specialized surgical instrumentation for use with urogynecologic surgical mesh is now regulated under 21 CFR 884.4910.

FDA finds good cause for issuing this amendment as a final rule without notice and comment because this rule only updates the identification of the device under § 876.4730 to reflect changes made in the recently issued final reclassification order for specialized surgical instrumentation for use with urogynecologic surgical mesh (5 U.S.C. 553(b)(B)). In addition, FDA finds good cause for this amendment to become effective on the date of publication of this action. The Administrative Procedure Act allows an effective date less than 30 days after publication as “provided by the agency for good cause found and published with the rule” (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the amendment to § 876.4730 does not impose any new regulatory requirements on affected parties. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good cause for this amendment to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 876

Gastroenterology-urology devices, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner

of Food and Drugs, 21 CFR part 876 is amended as follows:

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 1. The authority citation for part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Amend § 876.4730 by revising paragraph (a) to read as follows:

§ 876.4730 Manual gastroenterology-urology surgical instrument and accessories.

(a) *Identification.* A manual gastroenterology-urology surgical instrument and accessories is a device designed to be used for gastroenterological and urological surgical procedures. The device may be nonpowered, hand-held, or hand-manipulated. Manual gastroenterology-urology surgical instruments include the biopsy forceps cover, biopsy tray without biopsy instruments, line clamp, nonpowered rectal probe, nonelectrical clamp, colostomy spur-crushers, locking device for intestinal clamp, needle holder, gastro-urology hook, gastro-urology probe and director, nonself-retaining retractor, laparotomy rings, nonelectrical snare, rectal specula, bladder neck spreader, self-retaining retractor, and scoop. A manual surgical instrument that is intended specifically for use as an aid in the insertion, placement, fixation, or anchoring of surgical mesh during urogynecologic procedures are classified under § 884.4910 of this chapter.

* * * * *

Dated: February 23, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-03997 Filed 2-28-17; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-436]

Schedules of Controlled Substances: Placement of 10 Synthetic Cathinones Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Drug Enforcement Administration places 10 synthetic