and alcohol testing program is considered registered when the following information is submitted to the Flight Standards District Office nearest your principal place of business:

(i) Company name.

(ii) Telephone number.

(iii) Address where your drug and alcohol testing program records are kept.

(iv) Type of safety-sensitive functions you or your employees perform (such as flight instruction duties, aircraft dispatcher duties, maintenance or preventive maintenance duties, ground security coordinator duties, aviation screening duties, air traffic control duties).

(v) Whether you have 50 or more covered employees, or 49 or fewer covered employees.

(vi) A signed statement indicating that your company will comply with this part and 49 CFR part 40.

(2) This Letter of Authorization will satisfy the requirements for both your drug testing program under subpart E of this part and your alcohol testing program under this subpart.

(3) Update the Letter of Authorization information as changes occur. Send the updates to the Flight Standards District Office nearest your principal place of business.

(4) If you are a part 119 certificate holder with authority to operate under part 121 or part 135 and intend to begin operations as defined in § 91.147 of this chapter, you must also advise the Federal Aviation Administration, Office of Aerospace Medicine, Drug Abatement Division (AAM–800), 800 Independence Avenue SW., Washington, DC 20591.

(f) *Obtaining a Drug and Alcohol Testing Program Registration from the FAA.* (1) Except as provided in paragraphs (d) and (e) of this section, to obtain a Drug and Alcohol Testing Program Registration from the FAA you must submit the following information to the Office of Aerospace Medicine, Drug Abatement Division:

(i) Company name.

(ii) Telephone number.

(iii) Address where your drug and alcohol testing program records are kept.

(iv) Type of safety-sensitive functions you or your employees perform (such as flight instruction duties, aircraft dispatcher duties, maintenance or preventive maintenance duties, ground security coordinator duties, aviation screening duties, air traffic control duties).

(v) Whether you have 50 or more covered employees, or 49 or fewer covered employees.

(vi) A signed statement indicating that: your company will comply with this part and 49 CFR part 40; and you intend to provide safety-sensitive functions by contract (including subcontract at any tier) to a part 119 certificate holder with authority to operate under part 121 or part 135 of this chapter, an operator as defined in § 91.147 of this chapter, or an air traffic control facility not operated by the FAA or by or under contract to the U.S. military.

(2) Send this information to the Federal Aviation Administration, Office of Aerospace Medicine, Drug Abatement Division (AAM–800), 800 Independence Avenue SW., Washington, DC 20591.

(3) This Drug and Alcohol Testing Program Registration will satisfy the registration requirements for both your drug testing program under subpart E of this part and your alcohol testing program under this subpart.

(4) Update the registration information as changes occur. Send the updates to the address specified in paragraph (f)(2) of this section.

Issued under authority provided by 49 U.S.C. 106(f) and 45102 in Washington, DC, on July 1, 2013.

Michael P. Huerta,

Administrator.

[FR Doc. 2013–16852 Filed 7–12–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA–2013–N–0002]

Oral Dosage Form New Animal Drugs; Nicarbazin; Oclacitinib; Zilpaterol

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during May 2013. FDA is also informing the public of the availability of summaries the basis of approval and of environmental review documents, where applicable.

DATES: This rule is effective July 15, 2013.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9019, *ghaibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during May 2013, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.*

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING MAY 2013

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
141–279	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	NICARB 25% (nicarbazin) and BMD (bacitracin methylene disalicylate) Type A medicated articles.	Supplement revising nicarbazin dosage to a range consistent with dosage approved for use in combination feeds.	558.366	No	CE [1]

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING MAY 2013—Continued

NADA/ ANADA	Sponsor	New animal drug product name	Action	21 CFR section	FOIA summary	NEPA review
141–345	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	APOQUEL (oclacitinib tablet)	Original approval for control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.	520.1604	Yes	CE [1]
200–544	Huvepharma AD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	ZILMAX (zilpaterol hydrochloride) plus RUMENSIN (monensin) plus TYLOVET 100 (tylosin phosphate) plus MGA (melengestrol acetate) Type A medicated articles.	Original aapproval as a generic copy of NADA 141–280).	528.665	Yes	CE [1]

[1] The Agency has determined under 21 CFR 25.33 that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not individually or cumulatively have a significant effect on the human environment.

List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. Add § 520.1604 to read as follows:

§ 520.1604 Oclacitinib.

(a) *Specifications.* Each tablet contains 3.6, 5.4, or 16 milligrams (mg) of oclacitinib as oclacitinib maleate.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer orally 0.18 to 0.27 mg/per pound of body weight (0.4 to 0.6 mg/kg body weight) twice daily for up to 14 days; then administered once daily for maintenance therapy.

(2) *Indications for use.* For control of pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age.

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

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 4. In § 558.366, in paragraph (d), amend the table by:

■ a. Revising the entry for ''90.8 to 181.6 (0.01 to 0.02 pct)'', and

■ b. Removing the entry for ''Bacitracin methylene disalicylate 4 to 50'' under the heading ''113.5 (0.0125 pct)''; and

■ c. Removing the entry for ''Bacitracin methylene disalicylate 50'' under the heading ''113.5 (0.0125 pct)''.

The additions and revisions read as follows:

§ 558.366 Nicarbazin.

* * * * *

(d) * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	* *	* * *	
90.8 to 181.6 (0.01 to 0.02 pct).	.....	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton.	066104
	Bacitracin methylene disalicylate 4 to 50.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bacitracin methylene disalicylate 4 to 50 and roxarsone 22.7 to 45.4.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Discontinue medication 5 days before marketing birds for human consumption. Do not feed to laying hens. Nicarbazin as provided by No. 066104; bacitracin methylene disalicylate and roxarsone as provided by No. 054771 in § 510.600(c) of this chapter.	066104
	Bacitracin methylene disalicylate 30.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	066104
	Bacitracin methylene disalicylate 50.	Broiler chickens: As an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina, E. maxima, E. necatrix,* and *E. brunetti*) coccidiosis; as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard. Do not use as a treatment for coccidiosis. Do not feed to laying hens. Withdraw 4 days before slaughter for use levels at or below 113.5 g/ton. Withdraw 5 days before slaughter for use levels above 113.5 g/ton. Bacitracin methylene disalicylate as provided by No. 054771 in § 510.600(c) of this chapter.	054771
*	*	*	*	*	*	*

* * * * *

■ 5. In § 558.665, in the table, in paragraphs (e)(2), (e)(4), and (e)(6), revise the last sentence in the ''Limitations'' column and revise the ''Sponsor'' column to read as follows:

§ 558.665 Zilpaterol.

* * * * *

(e) * * *

Zilpaterol in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*	*	*
(2)	.....	.....	* * * Melengestrol acetate as provided by Nos. 000986 or 054771 in § 510.600(c) of this chapter.	000061 000986
*	*	*	*	*	*	*
(4)	.....	.....	* * * Monensin as provided by No. 000986; and melengestrol acetate as provided by Nos. 000986 or 054771 in § 510.600(c) of this chapter.	000061 000986
*	*	*	*	*	*	*
(6)	.....	.....	* * * Monensin as provided by No. 000986; tylosin as provided by Nos. 000986 or 016592; and melengestrol acetate as provided by Nos. 000986 or 054771 in § 510.600(c) of this chapter.	000061 000986 016592

Dated: July 1, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013–16258 Filed 7–12–13; 8:45 am]

BILLING CODE 4160–01–P