4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

[Docket No. FDA-2014-N-0002]

Zoetis Inc., et al.; Withdrawal of Approval of New Animal Drug Applications for Combination Drug Medicated Feeds Containing an Arsenical Drug

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal of approval.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal approval of 69 new animal drug applications (NADAs) and 22 abbreviated new animal drug applications (ANADAs) for use of arsanilic acid, carbarsone, or roxarsone Type A medicated articles to manufacture combination drug Type B and Type C medicated feeds. This action is being taken at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9079, john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Recently, the Agency provided notice of the withdrawal of approval of NADAs for Type A medicated articles containing arsanilic acid, carbarsone, and roxarsone and revoked applicable regulations for their conditions of use to manufacture single-

ingredient medicated feeds in 21 CFR part 558 New Animal Drugs For Use in Animal Feeds (78 FR 70062, November 22, 2013; 78 FR 69992, November 22, 2013; 78 FR 70566, November 26, 2013; 78 FR 70496, November 26, 2013).

Subsequently, the following six sponsors of NADAs and ANADAs permitting use of arsanilic acid, carbarsone, or roxarsone Type A medicated articles to manufacture combination drug Type B and Type C medicated feeds requested that FDA withdraw approval of their applications because these combination medicated feeds are no longer manufactured or marketed.

- Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007 has requested that FDA withdraw approval of the following 39 NADAs and 11 ANADAs:

NADA/ ANADA	Ingredient New Animal Drugs
040-435	3-NITRO (roxarsone)/DECCOX (decoquinate)
041-178	Roxarsone/AMPROL Plus (amprolium and ethopabate)/LINCOMIX (lincomycin)
041-984	Roxarsone/ROFENAID (sulfadimethoxine/ormetoprim)
091-326	3-NITRO (roxarsone)/DECCOX (decoquinate)/ALBAC (bacitracin zinc)
092-522	Roxarsone/COBAN (monensin)/LINCOMIX (lincomycin)
095-546	Roxarsone/ROBENZ (robenidine)
102-485	3-NITRO (roxarsone)/AVATEC (lasalocid)
105-758	3-NITRO (roxarsone)/AMPROL HI-E (amprolium and ethopabate)/BACIFERM (bacitracin zinc)
112-661	3-NITRO (roxarsone)/AVATEC (lasalocid)/LINCOMIX (lincomycin)
112-687	3-NITRO (roxarsone)/AVATEC (lasalocid)/FLAVOMYCIN (bambermycins)
116-082	3-NITRO (roxarsone)/AVATEC (lasalocid)/BMD (bacitracin MD)
116-088	3-NITRO (roxarsone)/COBAN (monensin)/BMD (bacitracin MD)
123-154	3-NITRO (roxarsone)/BACIFERM (bacitracin zinc)/COBAN (monensin)
126-052	3-NITRO (roxarsone)/AVATEC (lasalocid)/BACIFERM (bacitracin zinc)
131-894	3-NITRO (roxarsone)/AVATEC (lasalocid)/bacitracin MD
132-447	Roxarsone/BIO-COX (salinomycin)
134-185	3-NITRO (roxarsone)/BIO-COX (salinomycin)/FLAVOMYCIN (bambermycins)
135-321	3-NITRO (roxarsone)/BIO-COX (salinomycin)/BMD (bacitracin MD)
137-536	3-NITRO (roxarsone)/BIO-COX/ALBAC (bacitracin zinc)

NADA/ ANADA	Ingredient New Animal Drugs
138-703	3-NITRO (roxarsone)/COBAN (monensin)/ALBAC (bacitracin zinc)
139-190	3-NITRO (roxarsone)/BIO-COX (salinomycin)/BACIFERM (bacitracin zinc)
140-581	3-NITRO (roxarsone)/BIO-COX (salinomycin)/LINCOMIX (lincomycin)
140-852	3-NITRO (roxarsone)/MONTEBAN/BMD (bacitracin MD)
140-867	3-NITRO (roxarsone)/BIO-COX (salinomycin)/AUREOMYCIN (chlortetracycline)
141-100	3-NITRO (roxarsone)/DECCOX (decoquinate)/BMD (bacitracin MD)
141-112	3-NITRO (roxarsone)/MAXIBAN (narasin and nicarbazin)/BMD (bacitracin MD)
141-121	3-NITRO (roxarsone)/BIO-COX (salinomycin)/BMD (bacitracin MD)
141-131	3-NITRO (roxarsone)/ZOAMIX (zoalene)/BMD (bacitracin MD)
141-135	3-NITRO (roxarsone)/BIO-COX (salinomycin)
141-138	3-NITRO (roxarsone)/COBAN (monensin)/BMD (bacitracin MD)
141-139	3-NITRO (roxarsone)/COBAN (monensin)
141-142	3-NITRO (roxarsone)/AMPROL (amprolium)/BMD (bacitracin MD)
141-155	3-NITRO (roxarsone)/ROBENZ (robenidine)/BMD (bacitracin MD)
141-157	3-NITRO (roxarsone)/STENOROL (halofuginone)
141-223	3-NITRO (roxarsone)/CLINACOX (diclazuril)
141-293	3-NITRO (roxarsone)/AVATEC (lasalocid)
200-206	3-NITRO (roxarsone)/ALBAC (bacitracin zinc)/DECCOX (decoquinate)
200-207	3-NITRO (roxarsone)/ALBAC (bacitracin zinc)/COYDEN 25 (clopidol)
200-208	3-NITRO (roxarsone)/ALBAC (bacitracin zinc)/AVATEC (lasalocid)
200-209	3-NITRO (roxarsone)/ALBAC (bacitracin zinc)/SACOX (salinomycin)
200-214	3-NITRO (roxarsone)/ALBAC (bacitracin zinc)/AMPROL HI-E (amprolium and ethopabate)
200-211	3-NITRO (roxarsone)/ALBAC (bacitracin zinc)/COBAN (monensin)
200-215	3-NITRO (roxarsone)/ALBAC (bacitracin zinc)/BIO-COX (salinomycin)
200-217	3-NITRO (roxarsone)/ALBAC (bacitracin zinc)/AMPROL HI-E (amprolium and ethopabate)
200-259	3-NITRO (roxarsone)/SACOX (salinomycin)/CHLORMAX (chlortetracycline)
200-260	3-NITRO (roxarsone)/BIO-COX (salinomycin)/CHLORMAX (chlortetracycline)
038-879	CARB-O-SEP (carbarsone)/ZOAMIX (zoalene)
039-646	CARB-O-GAIN (carbarsone)/BMD (bacitracin MD)
136-484	CARB-O-SEP (carbarsone)/BACIFERM (bacitracin zinc)
200-203	CARB-O-SEP (carbarsone)/ALBAC (bacitracin zinc)

- Huvepharma AD, 5th Floor, 3A Nikolay Haitov Str., 1113 Sofia, Bulgaria has requested that FDA withdraw approval of the following 16 NADAs and 8 ANADAs:

NADA/ ANADA	Ingredient New Animal Drugs
013-461	3-NITRO (roxarsone)/AMPROL Plus (amprolium and ethopabate)
040-264	3-NITRO (roxarsone)/COYDEN 25 (clopidol)
041-541	3-NITRO (roxarsone)/COYDEN 25 (clopidol)/BMD (bacitracin MD)
044-016	Roxarsone/bacitracin Zinc/COYDEN 25 (clopidol)
049-179	Roxarsone/AMPROL HI-E (amprolium and ethopabate)
049-180	Roxarsone/AMPROL HI-E (amprolium and ethopabate)/BMD (bacitracin MD)
095-547	3-NITRO (roxarsone)/AMPROL HI-E (amprolium and ethopabate)/FLAVOMYCIN (bambermycins)
095-548	3-NITRO (roxarsone)/AMPROL (amprolium)/FLAVOMYCIN (bambermycins)
095-549	3-NITRO (roxarsone)/AMPROL (amprolium)/FLAVOMYCIN (bambermycins)
098-341	3-NITRO (roxarsone)/COBAN (monensin)/FLAVOMYCIN (bambermycins)
101-628	3-NITRO (roxarsone)/FLAVOMYCIN (bambermycins)/zoalene
140-533	3-NITRO (roxarsone)/STENOROL (halofuginone)/BMD (bacitracin MD)
140-843	3-NITRO (roxarsone)/MONTEBAN (narasin)/FLAVOMYCIN (bambermycins)
141-190	3-NITRO (roxarsone)/CLINICOX (diclazuril)/BMD (bacitracin MD)
200-080	3-NITRO (roxarsone)/SACOX (salinomycin)/FLAVOMYCIN (bambermycins)
200-081	3-NITRO (roxarsone)/SACOX (salinomycin)/BMD (bacitracin MD)
200-086	3-NITRO (roxarsone)/SACOX (salinomycin)/ALBAC (bacitracin zinc)
200-090	3-NITRO (roxarsone)/SACOX (salinomycin)/LINCOMIX (lincomycin)
200-091	3-NITRO (roxarsone)/SACOX (salinomycin)/AUREOMYCIN (chlortetracycline)
200-094	3-NITRO (roxarsone)/SACOX (salinomycin)/STAFAC (virginiamycin)
200-097	3-NITRO (roxarsone)/SACOX (salinomycin)
200-143	3-NITRO (roxarsone)/SACOX (salinomycin)/BACIFERM (bacitracin zinc)
118-507	CARB-O-SEP (carbarsone)/AMPROL (amprolium)
130-661	CARB-O-SEP (carbarsone)/FLAVOMYCIN (bambermycins)

- Phibro Animal Health Corp., GlenPointe Centre East, 3d floor, 300 Frank W. Burr Blvd., suite 21, Teaneck, NJ 07666 has requested that FDA withdraw approval of the following seven NADAs and two ANADAs:

NADA/ ANADA	Ingredient New Animal Drugs
107-997	Roxarsone/NICARB (nicarbazin)/LINCOMIX (lincomycin)
108-115	Roxarsone/NICARB (nicarbazin)
120-724	3-NITRO (roxarsone)/STAFAC (virginiamycin)/COBAN (monensin)
138-953	3-NITRO (roxarsone)/STAFAC (virginiamycin)/BIO-COX (salinomycin)
141-058	3-NITRO (roxarsone)/AVIAX (semduramycin)/BMD (bacitracin MD)
141-066	3-NITRO (roxarsone)/AVIAX (semduramycin)
141-226	Roxarsone/AVIAX (semduramycin)/STAFAC (virginiamycin)
200-170	3-NITRO (roxarsone)/NICARMIX 25 (nicarbazin)/LINCOMIX (lincomycin)
200-172	3-NITRO (roxarsone)/NICARMIX 25 (nicarbazin)

- Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285 has requested that FDA withdraw approval of the following four NADAs:

NADA	Ingredient New Animal Drugs
041-500	3-NITRO (roxarsone)/COBAN (monensin)
049-464	Roxarsone/monensin/bacitracin
140-445	Roxarsone/MONTEBAN (narasin)
141-113	3-NITRO (roxarsone)/MAXIBAN (narasin and nicarbazin)

- Cross Vetpharm Group Ltd., Broomhill Road, Tallaght, Dublin 24, Ireland, has requested that FDA withdraw approval of the following three NADAs:

NADA	Ingredient New Animal Drugs
038-241	PRO-GEN (arsanilic acid)/ERYTHRO (erythromycin)/zoalene
038-242	PRO-GEN (arsanilic acid)/ERYTHRO (erythromycin)/amprolium and ethopabate
038-624	PRO-GEN (arsanilic acid)/ERYTHRO (erythromycin)

- Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68144 has requested that FDA withdraw approval of the following ANADA:

ANADA	Ingredient New Animal Drugs

ANADA	Ingredient New Animal Drugs
200-355	3-NITRO (roxarsone)/PENNCHLOR (chlortetracycline)/BIO-COX (salinomycin)

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with 21 CFR 514.116 Notice of withdrawal of approval of application, notice is given that approval of the NADAs and ANADAs listed in this document, and all supplements and amendments thereto, is hereby withdrawn, effective [INSERT DATE 10 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 3, 2014.

Bernadette Dunham,

Director,

Center for Veterinary Medicine.

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