INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Elaine Lippmann, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6238, Silver Spring, MD 20993, 301–796–3600; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 25, 2019 (84 FR 57441), FDA published a notice with a 90-day comment period to request comments on the revised draft guidance for industry and staff entitled ''Drug Products Labeled as Homeopathic.'' FDA is extending the comment period, in response to a request from a stakeholder, until March 23, 2020. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without significantly delaying publication of the final version of the guidance.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: January 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00091 Filed 1–7–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5405]

Alaco, Inc., et al.; Proposal To Withdraw Approval of Seven New Animal Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Veterinary Medicine (CVM) is proposing to withdraw approval of seven new animal drug applications (NADAs) and is announcing an opportunity for the NADA holders to request a hearing on this proposal. The basis for the proposal is that the NADA holders have repeatedly failed to file required annual reports for those NADAs.

DATES: The NADA holders may submit a request for a hearing by February 7, 2020. Submit all data, information, and analyses upon which the request for a hearing relies March 9, 2020. Submit electronic or written comments by March 9, 2020.

ADDRESSES: The request for a hearing may be submitted by the NADA holders by either of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments to submit your request for a hearing. Comments submitted electronically to *https://www.regulations.gov,* including any attachments to the request for a hearing, will be posted to the docket unchanged.

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- Because your request for a hearing will be made public, you are solely responsible for ensuring that your request does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. The request for a hearing must include the Docket No. FDA–2019–N–5405 for ''Alaco, Inc., et al.; Proposal to Withdraw Approval of Seven New Animal Drug Applications; Opportunity for a Hearing.'' The request for a hearing will be placed in the docket and publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

The NADA holders may submit all data and analyses upon which the request for a hearing relies in the same manner as the request for a hearing except as follows:

- Confidential Submissions—To submit any data analyses with confidential information that you do not wish to be made publicly available, submit your data and analyses only as a written/paper submission. You should submit two copies total of all data and analyses. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of any decisions on this matter. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov* or available at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday. Submit both copies to the Dockets Management Staff. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law.

Comments Submitted by Other Interested Parties: For all comments submitted by other interested parties, submit comments as follows:

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 the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and

Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–N–5405 for ''Alaco, Inc., et al.; Proposal to Withdraw Approval of Seven New Animal Drug Applications; Opportunity for a Hearing.'' Received comments, those filed in a timely manner (see **DATES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vernon Toelle, Center for Veterinary Medicine (HFV–234), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5637.

SUPPLEMENTARY INFORMATION: The FDA's CVM is proposing to withdraw approval of seven new animal drug applications (NADAs) and is announcing an opportunity for the NADA sponsors to request a hearing on this proposal. The new animal drugs approved in these NADAs have not been marketed for several years. The establishments associated with these drug products are not registered under 21 CFR 207.21 nor are these drug products listed under 21 CFR 207.45. The basis for this proposal is that these NADA sponsors have repeatedly failed to submit annual drug experience reports to FDA concerning their approved NADA as required under § 514.80 (21 CFR 514.80). These sponsors have not responded to the Agency's requests, sent by certified mail, for submission of the reports. The delinquent approved NADAs and their sponsors are listed in table 1.

TABLE 1—APPROVED NADAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN SUBMITTED

Application No.	Trade name (drug)	Sponsor	Citation in 21 CFR
031–971	CUPRATE (cupric glycinate)	Walco International, Inc., 15 West Putnam, Porterville, CA 93257.	522.518
045–863	PALOSEIN (orgotein)	OXIS International, Inc., 6040 N Cutter Circle, Suite 317, Portland, OR 97217–3935.	522.1620
046–922	SERGEANTS SURE SHOT (n-butyl chloride) Capsules.	ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105.	520.260
046–923	SERGEANTS (n-butyl chloride) Puppy Worm Capsules.	ConAgra Pet Products Co., 3902 Leavenworth St., Omaha, NE 68105.	520.260
065–067	Tetracycline HCl Tablets	Premo Pharmaceutical Laboratories, Inc., 111 Leuning St., South Hackensack, NJ 07606.	Not codified
140–850	ELITE (dichlorophene and toluene) Dog & Cat Wormer.	RSR Laboratories, Inc., 501 Fifth St., Bristol, TN 37620.	520.580
141–107	BAPTEN for Injection (ß-aminopropionitrile fumarate).	Alaco, Inc., 1500 N Wilmot Rd., Suite 290–C, Tucson, AZ 85712.	522.84

Therefore, notice is given to the holders of the approved NADAs listed in table 1 and to all other interested persons that the Director of CVM proposes to issue an order, under section 512(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(e)), withdrawing approval of the NADAs and all amendments and supplements thereto on the grounds that the NADA holders have failed to submit the reports required under § 514.80. Upon withdrawal of approval of these NADAs, the regulations published pursuant to section 512(i) of the FD&C Act in 21 CFR 510.600, 520.260, 520.580, 522.84, 522.518, and 522.1620 will be revoked.

In accordance with section 512 of the FD&C Act and parts 12 and 514 (21 CFR parts 12 and 514), the NADA holders are hereby provided an opportunity for a hearing to show why the approval of the NADAs listed previously should not be withdrawn (and the corresponding regulations revoked) and an opportunity to raise, for administrative determination, all issues relating to the legal status of the new animal drug products covered by these NADAs.

An NADA holder who decides to seek a hearing must file the following: (1) A written notice of participation and a request for a hearing (see **DATES** and **ADDRESSES**) and (2) the data, information, and analyses relied on to justify a hearing (see **DATES** and **ADDRESSES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of

participation and request for a hearing, the information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 514.200 (21 CFR 514.200) and in part 12.

The failure of an NADA holder to file a timely written notice of participation and request for a hearing, as required by § 514.200 and part 12, constitutes an election by that NADA holder not to avail itself of the opportunity for a hearing concerning CVM's proposal to withdraw approval of the NADAs and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the NADAs, and the new animal drug products may not thereafter be lawfully introduced or delivered for introduction into interstate commerce. Any new animal drug product introduced or delivered for introduction into interstate commerce without an approved NADA, conditional approval, or index listing is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 514.80. If a request for a hearing is not complete or is not supported, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in two copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *https://www.regulations.gov.*

This notice is issued under section 512 of the FD&C Act and under authority delegated to the Principal Associate Commissioner for Policy by the Commissioner of Food and Drugs.

Dated: January 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00072 Filed 1–7–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–3592]

Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or Agency) is extending the comment period for the notice entitled ''Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff; Availability'' that appeared in the **Federal Register** of November 25, 2019. The Agency is taking this action to allow interested persons additional time to submit comments before finalization of the guidance.

DATES: FDA is extending the comment period on the notice published November 25, 2019 (84 FR 64906). Submit either electronic or written comments on the draft guidance by January 24, 2020, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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 the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–3592 for ''Certificates of Confidentiality; Guidance for Sponsors, Sponsor-Investigators, Researchers, Industry, and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://*