between programs by identifying gaps, weaknesses, and shortfalls in program design; and focusing on shared resources to reduce duplicative and burdensome processes.

Statutory Authority: Section 511 of the Title V of the Social Security Act, as added by Section 2951 of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), and amended by the Protecting Access to Medicare Act of 2014 (Pub. L. 113–93) and the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10).

Mary M. Wayland,

Senior Grants Policy Specialist, Division of Grants Policy, Office of Administration.

[FR Doc. 2016–01033 Filed 1–20–16; 8:45 am]

BILLING CODE 4184–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0839]

Target Animal Safety Data Presentation and Statistical Analysis; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry (GFI) #226 entitled ''Target Animal Safety Data Presentation and Statistical Analysis.'' The purpose of this document is to provide recommendations to industry regarding the presentation and statistical analyses of target animal safety (TAS) data submitted to the Center for Veterinary Medicine (CVM) as part of a study report to support approval of a new animal drug. These recommendations apply to TAS data generated from both TAS and field effectiveness studies conducted in companion animals (*e.g.,* dogs, cats, and horses) and food animals (*e.g.,* swine, ruminants, fish, and poultry).

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

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, 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–2015–D–0839 for Target Animal Safety Data Presentation and Statistical Analysis. Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://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 Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV–6), 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Virginia Recta, Center for Veterinary Medicine (HFV–160), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0840, *virginia.recta@fda.hhs.gov,*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 31, 2015 (80 FR 17047), FDA published the notice of availability for a draft guidance entitled ''Target Animal Safety Data Presentation and Statistical Analysis'' giving interested persons until June 1, 2015, to comment on the draft guidance. FDA received two comments on the draft guidance and those comments were considered as the guidance was finalized. Some of the suggested changes were incorporated, and additional editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated March 2015.

This GFI provides recommendations to industry regarding the presentation

and statistical analyses of target animal safety (TAS) data submitted to CVM as part of a study report to support approval of a new animal drug. These recommendations apply to TAS data generated from both TAS and field effectiveness studies conducted in companion animals (*e.g.,* dogs, cats, and horses) and food animals (*e.g.,* swine, ruminants, fish, and poultry).

II. Significance of Guidance

This level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Target Animal Safety Data Presentation and Statistical Analysis. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control number 0910–0032.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm* or *http://www.regulations.gov.*

Dated: January 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01098 Filed 1–20–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0119]

Determination That THORAZINE (Chlorpromazine Hydrochloride) Tablets and 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 or Agency) has determined that the 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: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6207, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants 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. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic 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 removed 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 safety or effectiveness reasons, 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.

Application No.	Drug	Applicant
NDA 009149	THORAZINE (chlorpromazine hydrochloride (HCl)) Tablet; Oral, 10 milligrams (mg); 25 mg; 50 mg; 100 mg; 200 mg.	GlaxoSmithKline.
NDA 016793	CYTARABINE (cytarabine) Injectable; Injection, 100 mg/vial; 500 mg/vial; 1 gram (g)/vial; 2 g/vial.	Teva Pharmaceuticals USA, Inc.
NDA 018343	CAPOTEN (captopril) Tablet; Oral, 37.5 mg; 75 mg; 150 mg	Par Pharmaceutical, Inc.
NDA 020845	INOMAX (nitric oxide) Gas; Inhalation, 100 parts per million	Ino Therapeutics, Inc.
NDA 021178	GLUCOVANCE (glyburide; metformin HCl) Tablet; Oral, 1.25 mg; 250 mg	Bristol-Myers Squibb
NDA 050443	BLENOXANE (bleomycin sulfate) Injectable; Injection, EQ 15 units base/vial; EQ 30 units base/vial.	Bristol-Myers Squibb
NDA 050526	STATICIN (erythromycin) Solution; Topical, 1.5%	Westwood-Squibb Pharmaceuticals, Inc.
NDA 050675	VANTIN (cefpodoxime proxetil) For Suspension; Oral, EQ 50 mg base/5 mL; EQ 100 mg base/5 mL.	Pharmacia & Upjohn Co.
NDA 203595	SUCLEAR (magnesium sulfate, polyethylene glycol 3350, potassium chloride, potassium sulfate, sodium bicarbonate, sodium chloride, sodium sulfate) Solution; Oral, 1.6 g, 210 g, 0.74 g, 3.13 g, 2.86 g, 5.6 g, 17.5 g.	Braintree Laboratories, Inc.
ANDA 061827	CLEOCIN (clindamycin palmitate HCl) For Solution; Oral, EQ 75 mg base/5 mL	Pharmacia & Upjohn Co.