I. Background

FDA is announcing the availability of a final guidance for industry entitled ''Core Patient-Reported Outcomes in Cancer Clinical Trials.'' This final guidance provides recommendations to sponsors regarding the collection of a core set of PROs in cancer clinical trials and related considerations for instrument selection and trial design. The final guidance recommendations supplement previous guidance on use of PRO measures in clinical trials by providing additional considerations specific to the cancer clinical trial setting. The final guidance is intended to facilitate generation of high-quality data on a core set of patient-reported symptom and functional impacts that are important contributors to a patient's health-related quality of life.

Although this final guidance focuses on PRO measures, some of the recommendations may be relevant to other clinical outcome assessments (*i.e.,* clinician-reported outcome, observer-reported outcome, performance outcome) in cancer clinical trials. The final guidance is specific to registration trials for anti-cancer therapies intended to demonstrate an effect on survival, tumor response, or delay in the progression of a malignancy.

Cancer clinical trials typically employ standardized efficacy assessments using overall survival and tumor measures, and safety assessments provided by clinician reporting of adverse events. FDA acknowledges the added value of incorporating PRO measurement of symptoms and functional impacts into the benefit/risk assessment in appropriately designed trials; however, heterogeneity in PRO assessment strategies has lessened the regulatory utility of PRO data from cancer trials. Systematic assessment of a core set of PROs can facilitate high-quality data on patient-reported symptoms and functional impacts. In published literature, FDA authors have previously described a core set of PROs that may be important contributors to a patient's health-related quality of life and that may be sensitive to the effect of the disease and treatment under study.

FDA is issuing this final guidance to provide FDA's current thinking on the core PROs, considerations for instrument selection to measure the core PROs, trial design considerations such as assessment frequency, and labeling considerations. The core PROs recommended in the guidance are disease-related symptoms, symptomatic adverse events, overall side effect impact summary measure, physical function, and role function.

In the **Federal Register** of June 10, 2021 (86 FR 30944), FDA announced the availability of the draft guidance of the same title dated June 2021. FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include recommendations to consult FDA when selecting adverse events for reporting, edits to include hematological malignancies, and minor, editorial changes to improve clarity.

This final guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This final guidance represents the current thinking of FDA on ''Core Patient-Reported Outcomes in Cancer Clinical Trials.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved 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. 3501–3521). The collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: October 11, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24111 Filed 10–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–P–0761]

Determination That TAVIST (Clemastine Fumarate) Tablet, 2.68 Milligrams, Was 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, Agency, or we) has determined that TAVIST (clemastine fumarate) tablet, 2.68 milligrams (mg), was 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 this drug product, and it will allow FDA to continue to approve ANDAs that refer to the product as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Awo Archampong-Gray, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6243, Silver Spring, MD 20993–0002, 301–796–0110, *Awo.Archampong-Gray@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved, and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act 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 known generally as the ''Orange Book.'' Under FDA regulations, drugs are 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).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

TAVIST (clemastine fumarate) tablet, 2.68 mg, is the subject of NDA 017661, held by Novartis Pharmaceuticals Corp. and initially approved on February 25, 1977. TAVIST (clemastine fumarate) tablet, 2.68 mg, is indicated for the relief of symptoms associated with allergic rhinitis such as sneezing, rhinorrhea, pruritus, and lacrimation. It is also indicated for the relief of mild, uncomplicated allergic skin manifestations of urticaria and angioedema.

TAVIST (clemastine fumarate) tablet, 2.68 mg, is currently listed in the ''Discontinued Drug Product List'' section of the Orange Book. In a letter dated February 13, 2004, Novartis Consumer Health, Inc., requested withdrawal of NDA 017661 for TAVIST (clemastine fumarate). In the **Federal Register** of March 4, 2005 (70 FR 10651), FDA announced that it was withdrawing approval of NDA 017661, effective April 4, 2005.

Pharmobedient Consulting, LLC, submitted a citizen petition dated February 21, 2024 (Docket No. FDA–2024–P–0761), under 21 CFR 10.30, requesting that the Agency determine whether TAVIST (clemastine fumarate) tablet, 2.68 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that TAVIST (clemastine fumarate) tablet, 2.68 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that TAVIST (clemastine fumarate) tablet, 2.68 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of TAVIST (clemastine fumarate) tablet, 2.68 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have found no information that would indicate that this drug product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list TAVIST (clemastine fumarate) tablet, 2.68 mg, in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. FDA will not begin procedures to withdraw approval of approved ANDAs that refer to this drug product. Additional ANDAs for this drug product may also be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 9, 2024.

Eric Flamm,

Acting Associate Commissioner for Policy.

[FR Doc. 2024–24103 Filed 10–17–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–2732]

Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method; Draft 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 draft document entitled ''Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat Method.'' The draft guidance document provides recommendations on the development of blood collection, processing, and storage systems (*e.g.,* blood bags with anticoagulant and additive solutions, empty bags for platelet pooling) used for the manufacture of blood and blood components intended for transfusion using the buffy coat (BC) method. This guidance is intended for manufacturers of blood collection, processing, and storage systems.

DATES: Submit either electronic or written comments on the draft guidance by December 17, 2024 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–2024–D–2732 for ''Recommendations for the Development of Blood Collection, Processing, and Storage Systems for the Manufacture of Blood Components Using the Buffy Coat