methods used to support regulatory submissions for finished tobacco products including substantial equivalence (SE) applications, premarket tobacco product applications (PMTA), and modified risk tobacco product applications (MRTPA). These recommendations include analytical testing of tobacco product constituents, ingredients, and additives, as well as stability testing of finished tobacco products. The principles in this guidance may also be used for finished tobacco product testing and reporting of harmful and potentially harmful constituents (HPHCs) in tobacco products and tobacco smoke.

The FD&C Act requires, among other things, premarket review for new tobacco products and modified risk tobacco products (see sections 910 and 911 (21 U.S.C. 387j and 21 U.S.C. 387k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)), and also reporting of HPHCs under section 904 of the FD&C Act (21 U.S.C. 387d). Information about constituents, for example, might be required by law or otherwise support the findings for premarket authorization. Regulatory submissions often contain data from analytical testing, such as data about ingredients, constituents, and additives. In standard practice, analytical testing is done through validation of the analytical method. In these cases, the applicant will want to use analytical methods that are sufficiently precise, accurate, selective, and sensitive. Validation involves documenting, through the use of specific laboratory investigations, that the performance characteristics of the method are suitable and reliable for the intended analytical applications, in terms of precision, accuracy, selectivity, and sensitivity. When finalized, this guidance is intended to help industry produce more consistent and reliable analytical data used to support regulatory submissions for finished tobacco products, such as SE applications, PMTAs, MRTPAs, and for finished tobacco product testing and reporting of HPHCs in tobacco products and tobacco smoke.

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Validation and Verification of Analytical Testing Methods used for Tobacco Products.'' 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

We believe that the information collection provisions in the draft guidance do not create a new burden for respondents. We believe the recordkeeping provisions are part of usual and customary business practice. Tobacco manufacturers would have in-house analysts or contractual agreements with outside analytical laboratories and suppliers, as applicable for the type of tobacco product, to address all these information collection provisions.

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. 3501–3521). The collections of information in section 910(c)(1)(A)(i) of the FD&C Act have been approved under OMB control number 0910–0768; the collections of information in section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) have been approved under OMB control number 0910–0673; and the collections of information in 21 CFR part 1107 have been approved under OMB control number 0910–0684, the collections of information in section 904(a)(3) of the FD&C Act have been approved under OMB control number 0910–0732.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/tobacco-products/products-guidance-regulations/rules-regulations-and-guidance, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 16, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27719 Filed 12–21–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1967]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Biosimilars User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by January 21, 2022.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0719. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Biosimilars User Fee Program

OMB Control Number 0910–0718—Revision

This information collection supports FDA's Biosimilars User Fee Program. The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) amended the Public Health Service Act (PHS Act) to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act (42 U.S.C. 262(k)), added by the BPCI Act, allows a company to apply for licensure of a biosimilar or interchangeable biological product (351(k) application). The BPCI Act also amended section 735 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g) to include 351(k) applications as a type of application under ''human drug application'' for the purposes of the prescription drug user fee provisions.

The Biosimilar User Fee Act of 2012 (BsUFA) authorizes FDA to assess and collect user fees for certain activities in connection with biosimilar biological

product development (BPD). BsUFA was reauthorized for an additional 5 years in August 2017 (BsUFA II). We developed the guidance entitled ''Assessing User Fees Under the Biosimilar User Fee Amendments of 2017'' to assist industry in understanding when fees are incurred and the process by which applicants can submit payments. The guidance also explains how respondents can request discontinuation from the BPD program as well as how respondents can request to move products to the discontinued section of the biosimilar list. Finally, the guidance provides information on the consequences of failing to pay BsUFA II fees as well as processes for submitting reconsideration and appeal requests. The guidance is available on the FDA website at: *https://www.fda.gov/media/134567/download.* The guidance was issued consistent with our good guidance practice regulations in § 10.115 (21 CFR 10.115), which provide for public comment at any time.

We also developed Form FDA 3792, the Biosimilars User Fee Cover Sheet, which is submitted by each new BPD entrant (identified via a new meeting request or investigational new drug (IND) submission) and for new biologics license applications (BLAs). Form FDA 3792 requests the minimum necessary information to identify the request, to determine the amount of the fee to be assessed, and to account for and track user fees. The form provides a cross-reference of the fees submitted for an activity with the actual submission or activity by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs and BLAs and to account for and track user fees associated with BPD meetings.

In addition to Form FDA 3792, the information collection includes an annual survey of all BsUFA II participants designed to provide information to FDA of anticipated BsUFA II activity in the upcoming fiscal year. This information helps FDA set appropriate annual BsUFA II fees.

For efficiency of Agency operations, we are consolidating related information collection currently approved in OMB control number 0910–0719. Specifically we are including our current commitment goals as set forth in the document ''BsUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022,'' which represents the product of FDA discussions with regulated industry and public stakeholders, as mandated by Congress. The document, referred to as the ''BsUFA II letter,'' is available on our website at: *https://www.fda.gov/downloads/ForIndustry/UserFees/BiosimilarUserFeeActBsUFA/UCM521121.pdf.* The performance and procedural goals specified in the BsUFA II letter apply to aspects of the biosimilar biological product review program that are important for facilitating timely access to safe and effective biosimilar medicines for patients. Among those considerations is providing feedback to requests from regulated industry. Each year, FDA review staff participate in many meetings with requesters who seek advice relating to the development and review of a biosimilar or interchangeable product. Because these meetings often represent critical points in the regulatory and development process, it is important that there are clear procedures for the timely and effective conduct of such meeting. Accordingly, we issued draft guidance, ''Formal Meetings Between the FDA and Sponsors or Applicants of BsUFA Products,'' available on our website at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/formal-meetings-between-fda-and-sponsors-or-applicants-bsufa-products-guidance-industry.* The guidance was issued consistent with Section I, Part 6 of the BsUFA II letter (see p. 25), and with our good guidance practice regulations in § 10.115, which provide for public comment at any time. The guidance provides procedural instruction helpful to respondents and helps us reach what we believe is a more accurate burden estimate for the information collection.

Also available from our website is our Biosimilars Action Plan (BAP), which discusses key actions the Agency is taking to encourage innovation and competition among biologics and the development of biosimilars. The BAP builds on progress in implementing the approval pathway for biosimilar and interchangeable products, and provides interested persons with updates and resource material.

In the **Federal Register** of September 17, 2021 (86 FR 51900), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

FDA form; survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Biosimilar User Fee Cover Sheet (Form FDA 3792) ..	60	1	60	0.5 (30 minutes)	30
Annual Survey	60	1	60	1	60
Request for discontinuation from BPD program	10	1	10	1	10
Request to move products to discontinued section of the Biosimilar List.	5	1	5	0.5 (30 minutes)	2.5
Biosimilar product applications (351(k)(2)(A))	4	2.25	9	860	7,740
Interchangeable product applications (351(k)(2)(B)) ...	2	1	2	860	1,720
Patent infringement notifications	4	2.25	9	2	18
Formal Meetings Guidance for Industry Recommendations.	69	2.30	159	21.42	3,405
Total	.....	.....	314	.....	12,985.5

In anticipation of increased participation in the BPD program, we have adjusted our estimate to reflect an increase in the number of respondents since last OMB review. We have also made adjustments to reflect information collection consolidated from OMB control number 0910–0719. We invite comment on our estimates and assumptions.

Dated: December 15, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–27680 Filed 12–21–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–P–0375]

Determination That Alcohol and Dextrose Injection, 5 Milliliters/100 Milliliters, 5 Grams/100 Milliliters; and 10 Milliliters/100 Milliliters, 5 Grams/100 Milliliters, Were 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 Alcohol and Dextrose Injection, 5 milliliters (mL)/100 mL, 5 gram (g)/100 mL; and Alcohol and Dextrose Injection, 10 mL/100 mL, 5 g/100 mL, were withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL; and 10 mL/100 mL, 5 g/100 mL.

FOR FURTHER INFORMATION CONTACT: Kaetochi Okemgbo, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6272, Silver Spring, MD 20993–0002, 240–825–9944, *Kaetochi.Okemgbo@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.

Between 1938 and 1968, FDA evaluated NDAs solely on the basis of safety information. In 1962, the Kefauver-Harris Drug Amendments (Pub. L. 87–781) amended the FD&C Act to require that new drug products also be shown to be effective in order to obtain approval of an NDA. After the enactment of the Kefauver-Harris Drug Amendments, FDA initiated the Drug Efficacy Study Implementation (DESI) to evaluate the effectiveness of drug products that had been approved between 1938 and 1962 solely on the basis of safety.

FDA introduced the concept of an ''abbreviated new drug application'' in 1968 as a vehicle for approval of certain drugs affected by the DESI review. When a drug product subject to the DESI review was determined to be effective for one or more indications, FDA would issue a **Federal Register** notice for that drug product describing the DESI review findings and stating whether abbreviated new drug applications that met specified criteria could be submitted to FDA (see generally 35 FR 11273 (July 14, 1970); 35 FR 6574 (April 24, 1970)) for products that had not been marketed under an NDA. Such a finding allowed manufacturers to submit an abbreviated new drug application in lieu of an NDA. For approval of these applications, which were submitted before the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments) (Pub. L. 98–417) created the current ANDA pathway, FDA relied on the evidence of effectiveness that had been provided, reviewed, and accepted during the DESI process and evaluated the safety of these drug products on the basis of information included in NDAs submitted prior to 1962, as well as the subsequent marketing experience with the drugs. These applications are referred to as pre-Hatch-Waxman abbreviated new drug applications or ''PANDAs''.[1] PANDAs were submitted under section 505(b) of the FD&C Act and approved for safety and effectiveness under section 505(c) of the FD&C Act (see 86 FR 44731 at 44732 (August 13, 2021)).

As explained above, the current ANDA pathway is described in section 505(j) of the FD&C Act. Because of substantive differences in the application approval pathway for PANDAs, which were approved for safety and effectiveness under section 505(c) of the FD&C Act, compared to ANDAs approved under section 505(j) of the FD&C Act, FDA has determined that PANDA products can serve as reference listed drugs for 505(j) ANDA applicants seeking to make generic versions of these products and that there is a finding of safety and effectiveness that may be relied upon for approval by applicants of 505(b)(2) applications.

Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL; and 10 mL/100 mL, 5 g/100 mL, is the subject of NDA 004589, held by B. Braun Medical Inc. The initial application, which included Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL, was allowed to take effect on February 21, 1942. Alcohol and Dextrose Injection, 10 mL/100 mL, 5 g/100 mL, was allowed to take effect in a supplemental application on January 17, 1946. On July 28, 1972, FDA published a **Federal Register** notice regarding the DESI review of NDA 004589 (see 37 FR 15184). Under the DESI review, FDA concluded that there was substantial evidence of efficacy for two formulations of 5 percent Alcohol and 5 percent Dextrose for the indication ''for increasing caloric intake.'' Based on the **Federal Register** notice, FDA approved Alcohol and Dextrose Injection, 5 mL/100 mL, 5 g/100 mL in three PANDAs: ANDA 083263, held by Hospira, Inc. and initially approved on February 26, 1974; ANDA 083483, held by Miles Laboratories Inc. and originally approved on November 22, 1974; and

[1] See ''Drug Products Approved in Abbreviated New Drug Applications Before the Enactment of the Hatch-Waxman Amendments; Establishment of a Public Docket; Request for Comments,'' 86 FR 44731 (August 13, 2021). Note that the scope of the referenced notice is limited to drug products approved in PANDAs under section 505 of the FD&C Act prior to the Hatch-Waxman Amendments; the notice does not cover applications for antibiotic drug products that were originally submitted under section 507 of the FD&C Act (21 U.S.C. 357).