ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
APSR	232	1	76.58	17,766.56
CFSP	232	1	120.25	27,898
CFS–101, Parts I, II, and III	232	1	4.38	1,016.16
Caseworker Visits	52	1	99.33	5,165.16
Estimated Total Annual Burden Hours:				51,845.88

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–29083 Filed 12–4–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0823]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Over-the-Counter Drugs; Labeling Requirements

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: Fax written comments on the collection of information by January 6, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0340. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *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.

Over-the-Counter Drugs; Labeling Requirements—(OMB Control Number 0910–0340)—Extension

In the **Federal Register** of March 17, 1999, (64 FR 13254) (the 1999 labeling final rule), we amended our regulations governing requirements for human drug products to establish standardized format and content requirements for the labeling of all marketed over-the-counter (OTC) drug products in part 201 (21 CFR part 201). The regulations in part 201 require OTC drug product labeling to include uniform headings and subheadings, presented in a standardized order, with minimum standards for type size and other graphical features. Specifically, the 1999 labeling final rule added new § 201.66 (21 CFR 201.66) to part 201. Section 201.66 sets content and format requirements for the Drug Facts portion of labels on OTC drug products.

On June 20, 2000 (65 FR 38191), we published a **Federal Register** final rule that required all OTC drug products marketed under the OTC monograph system to comply with the labeling requirements in § 201.66 by May 16, 2005, or sooner (65 FR 38191 at 38193). Currently marketed OTC drug products are already required to be in compliance with these labeling requirements, and thus will incur no further burden to comply with Drug Facts labeling requirements in § 201.66. Modifications of labeling already required to be in Drug Facts format are usual and customary as part of routine redesign practice, and thus do not create additional burden within the meaning of the Paperwork Reduction Act of 1995 (the PRA). Therefore, the burden to comply with the labeling requirements in § 201.66 is a one-time burden applicable only to new OTC drug products introduced to the marketplace under new drug applications, abbreviated new drug applications, or an OTC drug monograph, except for products in ''convenience size'' packages.[1] New OTC drug products

[1] In a final rule published in the **Federal Register** of April 5, 2002 (67 FR 16304), the Agency delayed the compliance dates for the 1999 labeling final rule for all OTC drug products that: (1) Contain no more than two doses of an OTC drug; and (2) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear labeling to meet the requirements

Continued

must comply with the labeling requirements in § 201.66 as they are introduced to the marketplace.

Based on a March 1, 2010, estimate provided by the Consumer Healthcare Products Association (75 FR 49495 at 49496), we estimated that approximately 900 new OTC drug product stock keeping units (SKUs) are introduced to the marketplace each year. We estimated that these SKUs are marketed by 300 manufacturers. We estimated that the preparation of labeling for new OTC drug products would require 12 hours to prepare, complete, and review prior to submitting the new labeling to us. Based on this estimate, the annual reporting burden for this type of labeling is approximately 10,800 hours.

OTC sunscreen products were previously not included in our consideration of the burden to comply with the Drug Facts labeling requirements in § 201.66. We specifically exempted OTC sunscreen products from complying with the 1999 labeling final rule until we lifted the stay of the sunscreen final rule published in the **Federal Register** of May 21,1999 (64 FR 27666). In the **Federal Register** of December 31, 2001 (66 FR 67485), we stayed the 1999 sunscreen final rule indefinitely. Additionally, in the **Federal Register** of September 3, 2004 (69 FR 53801), we delayed the § 201.66 labeling implementation date for OTC sunscreen products indefinitely, pending future rulemaking to amend the substance of labeling for these products. In the **Federal Register** of August 27, 2007 (72 FR 49070), we proposed changes to labeling and related testing requirements for sunscreen products to address both ultraviolet A and ultraviolet B radiation, and we anticipated that sunscreen products would become subject to § 201.66 at the time any resultant final rule becomes effective. In the **Federal Register** of June 17, 2011 (76 FR 35620), we published a final rule that established testing and labeling requirements for OTC sunscreen products. This 2011 final rule lifted the delay of the § 201.66 labeling implementation date for OTC sunscreen product. The compliance dates for the 2011 final rule were June 18, 2012, for sunscreen products with annual sales of $25,000 or more and June 17, 2013, for sunscreen products with annual sales of less than $25,000, but we later delayed these compliance dates to December 17, 2012, and December 17, 2013, respectively, when we published an extension date notice on May 11, 2012 (77 FR 27591).

All currently marketed sunscreen products are, therefore, already required to be in compliance with the Drug Facts labeling requirements in§ 201.66, and thus will incur no further burden under the information collection provisions in the 1999 labeling final rule. However, a new OTC sunscreen drug product, like any new OTC drug product, will be subject to a one-time burden to comply with Drug Facts labeling requirements in § 201.66. We estimated that 60 new SKUs of OTC sunscreen drug products would be marketed each year (77 FR 27234). We estimated that these 60 SKUs would be marketed by 30 manufacturers. We estimated that approximately 12 hours would be spent on each label, based on the most recent estimate used for other OTC drug products to comply with the 1999 Drug Facts labeling final rule, including public comments received on this estimate in 2010 that addressed sunscreens.

In determining the burden for § 201.66, it is also important to consider exemptions or deferrals of the regulation allowed products under § 201.66(e). Since publication of the 1999 labeling final rule, we have received only one request for exemption or deferral. One response over an 8-year period equates to an annual frequency of response equal to 0.125. In the 1999 labeling final rule, we estimated that a request for deferral or exemption would require 24 hours to complete (64 FR 13254 at 13276). We continue to estimate that this type of response will require approximately 24 hours. Multiplying the annual frequency of response (0.125) by the number of hours per response (24) gives a total response time for requesting exemption or deferral equal to 3 hours.

In the **Federal Register** of July 23, 2013 (78 FR 44124), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received one comment in response to the notice. The comment was a complaint about the ''deceptively large'' containers in which some OTC drug products are packaged. These deceptively large containers mislead consumers into thinking that they were purchasing more product than the package actually contained.

We do not consider this comment relevant to this proposed collection of information. This information collection concerns OTC drug product labeling format and content, specifically the labeling that appears within the Drug Facts panel. This comment is a complaint about OTC drug products packaged in ''deceptively large'' containers, which is a separate issue and is not the subject of this notice. The regulations for Drug Facts labeling in § 201.66 do not establish, and were not intended to establish, container size requirements for OTC drug products. The Federal Food, Drug, and Cosmetic Act already prohibits the use of deceptively large containers. According to 21 U.S.C. 352(i): ''A drug or device shall be deemed to be misbranded if it is a drug and its container is so made, formed, or filled as to be misleading.'' Therefore, the commenter's complaint is already addressed by statute.

FDA estimates the current burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
201.66(c) and (d) for new OTC drug products	300	3	900	12	10,800
201.66(c) and (d) for new OTC sunscreen products	20	3	60	12	720
201.66(e)	1	0.125	0.125	24	3
Total					11,523

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

set forth in § 201.66(d)(1) and (d)(9) and, therefore, qualify for the labeling modifications currently set forth in § 201.66(d)(10) (67 FR 16304 at 16306). The Agency issued this delay in order to develop additional rulemaking for these ''convenience size'' products (December 12, 2006; 71 FR 74474). These products are not currently subject to the requirements of § 201.66. PRA approval for any requirements to which they may be subject in the future will be handled in a separate rulemaking.

Dated: November 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–29079 Filed 12–4–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1464]

Draft Guidance for Industry on Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.'' This guidance provides recommendations to applicants planning to include bioequivalence (BE) information in abbreviated new drug applications (ANDAs) and ANDA supplements. The guidance describes how to meet the BE requirements set forth in FDA regulations. The guidance is applicable to dosage forms intended for oral administration and to non-orally administered drug products in which reliance on systemic exposure measures is suitable for documenting BE. The guidance will be especially useful when planning BE studies intended to be conducted during the postapproval period for certain changes in an ANDA.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 5, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments to *http://www.regulations.gov.* Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Teresa Ramson, Center for Drug Evaluation and Research, Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 240–402–3870.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.'' The guidance is applicable to dosage forms intended for oral administration, including tablets, capsules, solutions, suspensions, conventional/immediate release, and modified (extended, delayed) release drug products, and to non-orally administered drug products in which reliance on systemic exposure measures is suitable for documenting BE (e.g., transdermal delivery systems and certain rectal and nasal drug products).

This guidance revises parts of the guidances to industry on ''Bioavailability and Bioequivalence Studies for Orally Administered Drug Products—General Considerations,'' and ''Food-Effect Bioavailability and Fed Bioequivalence Studies Relating to BE studies in ANDAs.'' Specifically, the draft guidance revises recommendations related to (1) the use of systemic exposure measures and (2) considerations for the conduct of BE studies under fed conditions. Revisions are based primarily on experience gained with recommendations contained in prior guidances as well as on scientific information that has become available to the Agency. We believe the revisions will clarify guidance to applicants conducting BE studies for systemically bioavailable generic drug products. This draft guidance contains recommendations for submission of BE studies for ANDAs only. A separate guidance entitled ''Bioavailability and Bioequivalence Studies Submitted in NDAs or INDs—General Considerations'' to address investigational new drugs (INDs), new drug applications (NDAs), and NDA supplements will be published in the near future. FDA has determined that separating guidances according to application type will be beneficial to sponsors.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on BE studies with pharmacokinetic endpoints for drug products submitted in ANDAs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that 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). Information submitted in an ANDA under 21 CFR 314.94(a)(7), supplemental applications submitted under 21 CFR 314.70(b), and waiver requests submitted under 21 CFR 314.90 are approved under OMB control number 0910–0001.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: November 29, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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