are subject to delays due to heightened security precautions. Thus, comments instead should be sent by facsimile to (202) 395–5167.

David C. Shonka,

Principal Deputy General Counsel.

[FR Doc. 2013–17560 Filed 7–22–13; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Interest Rate on Overdue Debts

Section 30.18 of the Department of Health and Human Services' claims collection regulations (45 CFR Part 30) provides that the Secretary shall charge an annual rate of interest, which is determined and fixed by the Secretary of the Treasury after considering private consumer rates of interest on the date that the Department of Health and Human Services becomes entitled to recovery. The rate cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the ''Schedule of Certified Interest Rates with Range of Maturities'' unless the Secretary waives interest in whole or part, or a different rate is prescribed by statute, contract, or repayment agreement. The Secretary of the Treasury may revise this rate quarterly. The Department of Health and Human Services publishes this rate in the **Federal Register**.

The current rate of 10⅜% as fixed by the Secretary of the Treasury, is certified for the quarter ended June 30, 2013. This rate is based on the Interest Rates for Specific Legislation, ''National Health Services Corps Scholarship Program (42 U.S.C. 254o(b)) and ''National Research Service Award Program (42 U.S.C. 288(c)(4)(B)).'' This interest rate will be applied to overdue debt until the Department of Health and Human Services publishes a revision.

Dated: July 12, 2013.

Margie Yanchuk,

Director, Associate Deputy Assistant Secretary.

[FR Doc. 2013–17683 Filed 7–22–13; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0823]

Agency Information Collection Activities: Proposed Collection; Comment Request; Format and Content Requirements for Over-the-Counter Drug Product Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the standardized format and content requirements for the labeling of over-the-counter (OTC) drug products.

DATES: Submit either electronic or written comments on the collection of information by September 23, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Format and Content Requirements for OTC Drug Product Labeling—(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 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 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 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 (NDAs), abbreviated new drug applications (ANDAs), or an OTC drug monograph, except for products in ''convenience size'' packages.[1] New OTC drug products 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 hour per response (24) gives a total response time for requesting exemption or deferral equal to 3 hours.

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.

[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 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: July 16, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–17548 Filed 7–22–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0403]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Protection of Human Subjects: Informed Consent; Institutional Review Boards

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 August 22, 2013.

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–NEW and title ''Protection of Human Subjects: Informed Consent; Institutional Review Boards.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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.

Protection of Human Subjects: Informed Consent; Institutional Review Boards—(OMB Control Number 0910–NEW)

Part 50 (21 CFR part 50) applies to all clinical investigations regulated by FDA under sections 505(i) and 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i) and 360j(g), respectively), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA, including foods and dietary supplements that bear a nutrient content claim or a health claim, infant formulas, food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. Compliance with part 50 is intended to protect the rights and safety of subjects involved in investigations filed with the FDA under sections 403, 406, 409, 412, 413, 502, 503, 505, 510, 513–516, 518–520, 721, and 801 of the FD&C Act (21 U.S.C. 343, 346, 348, 350a, 350b, 352, 353, 355, 360, 360c–360f, 360h–360j, 379e, and 381, respectively) and sections 351 and 354–360F of the Public Health Service Act.

With few exceptions, no investigator may involve a human being as a subject in FDA-regulated research unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (see § 50.20). In seeking informed consent, each subject must be provided with certain elements of informed consent. Those elements are listed in § 50.25. Informed consent shall be documented in writing as described in § 50.27.

An institutional review board (IRB) may approve emergency research without requiring the informed consent of all research subjects provided the IRB finds and documents that certain criteria are met as required in § 50.24. We estimate that about five times per year an IRB is requested to review emergency research under § 50.24. We estimate, of the five yearly requests for IRB review under § 50.24, a particular IRB will take about an hour during each of three separate fully convened IRB meetings to review the request under § 50.24 (one meeting occurring after community consultation). The total annual reporting burden for IRB review of emergency research under § 50.24 is estimated at 15 hours (see table 1).

The information requested in the regulations for exception from the general requirements for informed consent for medical devices (21 CFR 812.47), and the information requested in the regulations for exception from the general requirements of informed consent in 21 CFR 50.23, paragraphs (a) through (c), and (e), is currently approved under OMB control number 0910–0586. The information requested in the investigational new drug (IND) regulations concerning exception from informed consent for emergency research under § 50.24 is currently approved under OMB control number 0910–0014. In addition, the information requested in the regulations for IND safety reporting requirements for human drug and biological products and safety reporting requirements for bioavailability and bioequivalence studies in humans (21 CFR 320.31(d) and 312.32(c)(1)(ii) and (c)(1)(iv)) is currently approved under OMB control number 0910–0672.

Some clinical investigations involving children, although otherwise not approvable, may present an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (see § 50.54). Certain clinical investigations involving children may proceed if the IRB finds and documents that the clinical investigation presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children and when the Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines and following opportunity for public review and comment, makes a determination that certain conditions are met (see § 50.54(b)).

The information requested for clinical investigations in children of FDA-regulated products is covered by the collections of information in the IND regulations (part 312 (21 CFR part 312)), the investigational device exemption (IDE) regulations (part 812 (21 CFR part 812)), the IRB regulations (21 CFR 56.115), the food additive petition and nutrient content claim petition regulations (21 CFR 101.69 and 101.70), and the infant formula regulations (21 CFR parts 106 and 107)), all of which are approved by OMB. Specifically, the information collected under the IND regulations is currently approved under OMB control number 0910–0014. The information collected under the IDE regulations is currently approved under OMB control number 0910–0078. The information collected under the IRB regulations is currently approved under OMB control number 0910–0130. The information collected in food additive and nutrient content claim petitions is currently approved under OMB control number 0910–0381 (general requirements) and 0910–0016 (FDA Form 3503). The information collected under the infant formula regulations is currently approved under OMB control number 0910–0256 (general requirements) and 0910–0188 (infant formula recalls).

Part 56 (21 CFR part 56) contains the general standards for the composition, operation, and responsibility of an IRB