DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0377]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tobacco Health Document Submission

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 September 13, 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 0910–0654. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *daniel.gittleson@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.

Tobacco Health Document Submission—(OMB Control Number 0910–0654)—Extension

On June 22, 2009, the President signed the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Pub. L. 111–31) into law. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding, among other things, a new chapter granting FDA important authority to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors. The Tobacco Control Act created many new requirements for the tobacco industry. Section 101 of the Tobacco Control Act amended the FD&C Act by adding, among other things, section 904(a)(4) (21 U.S.C. 387d(a)(4)).

Section 904(a)(4) of the FD&C Act requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, ''that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives'' (herein referred to as ''tobacco health documents'').

FDA announced the availability of a guidance on this collection in the **Federal Register** of April 20, 2010 (75 FR 20606), and requested tobacco health documents that were created during the period from June 23, 2009, through December 31, 2009. The guidance stated that information required under section 904(a)(4) of the FD&C Act must be submitted to FDA beginning December 22, 2009. Further, FDA stated it would publish a revised guidance specifying the timing of subsequent reporting. FDA is in the process of revising the April 2010 guidance but will continue collecting documents created during the specified period from any manufacturers, importers, or their agents who still have documents to submit.

FDA has been collecting the information submitted under section 904(a)(4) of the FD&C Act through a facilitative electronic form and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic method. In both forms, FDA is requesting the following information from firms that have not already reported or still have documents to report:

- Submitter identification: Submitter type, company name, address, country, company headquarters Dun and Bradstreet number, and company headquarters Facility Establishment Identifier number;
- Submitter point of contact: Contact name, title, position title, email, telephone, and fax; and
- Submission format and contents (as applicable):
  - Electronic documents: Media type, media quantity, size of submission, quantity of documents, file type, and file software;
  - Paper documents: Quantity of documents, quantity of volumes, and quantity of boxes; and
  - Whether or not a submission is being provided.
- Confirmation statement (with identification and signature of submitter including name, company name, address, position title, email, telephone, and fax); and
- Document categorization (as applicable): Relationship of the document or set of documents to the following:
  - Health, behavioral, toxicological, or physiological effects;
  - Specific current or future tobacco product(s);
  - Class of current or future tobacco product(s);
  - Specific ingredient(s), constituent(s), component(s), or additive(s);
  - Class of ingredient(s), constituent(s), component(s), or additive(s).
- Document readability and accessibility: Keywords; glossary or explanation of any abbreviations, jargon, or internal (e.g., code) names; special instructions for loading or compiling submission; and
- Document metadata: Date document was created, document author(s), document recipient(s), document custodian, document title or identification number, beginning and ending Bates numbers, and Bates number ranges for documents attached to a submitted email.

In addition to the electronic and paper forms, the guidance that FDA issued in April 2010 (75 FR 20606) was intended to assist persons making tobacco health document submissions. For further assistance, FDA is providing a technical guide, embedded hints, and a Web tutorial on the electronic portal.

The estimated 50 hours per response burden is based on the average burden estimate among all four respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 50 hours estimate because it is an average value. FDA currently is evaluating the classification/coding recommendations and will revisit this issue in future guidance. The number of documents received each year since the original collection period has fallen to less than 5 percent of the number received in the original collection period. FDA expects this is because documents created within the specified period have already been submitted. Also, the number of respondents who still have documents to submit has decreased. Therefore, FDA estimates the biannual burden of the continuation of this collection to be at most, 5 percent of the original burden.

In the **Federal Register** of April 10, 2013 (78 FR 21379), FDA published a 60-day notice requesting public

comment on the proposed collection of information. FDA received five comments; some comments raised more than one issue. Comments relevant to the information request are addressed in this document.

(Comment 1) One comment indicated that the intent of the notice was unclear and suggested that FDA revise and republish the notice to provide clarity and allow stakeholders more opportunity to comment.

(Response) FDA published the 60-day information collection notice (78 FR 21379) to provide an opportunity for comment on its proposed extension of an existing collection of information. The collection includes health tobacco documents created during the period June 23, 2009, through December 31, 2009, that have not been submitted to FDA. FDA does not believe that revision of the April 2013 notice would add clarity or provide a more meaningful opportunity to comment. FDA has met the requirements for the proposed extension of this collection of information.

(Comment 2) Another comment stated that FDA is outside its statutory authority in recommending coding/classification and places an unnecessary and unreasonable burden on the industry with no benefit to FDA in collecting this information.

(Response) Section 904(a)(4) of the FD&C Act grants FDA the authority to collect health document information as specified in this document. The classification and coding mentioned in this document are recommendations from the April 2010 guidance, and FDA will reevaluate and revisit this issue in developing future guidance.

(Comment 3) Two comments indicated that the timing and burden for this collection are underestimated.

(Response) The estimated burden of 50 hours per response is based on the average burden estimate among four respondents. Therefore, on an individual basis, the actual burden per respondent may be higher or lower than the 50 hours estimate because it is an average value. FDA notes that the number of documents received since the original collection period has decreased each year and is currently less than 5 percent of the number received in the year following the Agency's original announcement. FDA expects that this collection of information will decrease by 7,600 hours because most documents created within the specified period have been submitted, and the number of respondents who still have documents to submit has decreased. Therefore, FDA estimates the biannual burden of the continuation of this collection to be, at most, 5 percent of the original burden.

(Comment 4) One comment indicated that the information requested in this collection is from too narrow a collection window, and another comment stated that the collection of 2009 information in 2013 is not necessary.

(Response) Section 904(a)(4) of the FD&C Act sets out an ongoing requirement for the submission of tobacco health documents. FDA is in the process of revising the April 2010 guidance to specify the timing of subsequent submissions. However, the Agency will continue collecting documents created during the period from June 23, 2009, through December 31, 2009, from any manufacturers, importers, or their agents who still have documents to submit.

(Comment 5) Several comments referred to the 2009 draft guidance (74 FR 68629, December 28, 2009) and to previously submitted comments on the 2009 draft guidance.

(Response) The 2009 draft guidance was superseded by publication of the April 2010 guidance. FDA considered comments on the 2009 draft guidance while developing the April 2010 guidance. Comments on Agency guidance are welcome at any time (21 CFR 10.115(g)(5)), and comments submitted on the April 2010 guidance will be considered when the guidance is revised.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Tobacco Health Document Submissions and Form FDA 3743	4	2	8	50	400

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

Dated: August 8, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0842]

Consolidation of Wound Care Products Containing Live Cells

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is transferring oversight responsibilities for certain wound care products containing live cells from the Center for Devices and Radiological Health (CDRH) to the Center for Biologics Evaluation and Research (CBER). This consolidation initiative provides the opportunity to further develop and coordinate scientific and regulatory activities between CDRH and CBER. FDA believes that as more wound care products containing live cells are developed such consolidation is necessary for both efficient and consistent Agency action.

FOR FURTHER INFORMATION CONTACT: John Barlow Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5130, Silver Spring, MD 20993, 301–796–8930, *john.weiner@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Consolidation of Approved Wound Care Products Containing Live Cells in CBER

On August 14, 2013, primary responsibility for regulating the following approved products: P950032, P960007, P000036, P010016, (all with product code MGR); H990013 (product code PBD); and H990002 (product code OCE), and all supplements included therein, was transferred from the Office of Device Evaluation, CDRH, to the Office of Cellular, Tissue and Gene Therapies, CBER. The jurisdictional assignment of these products to CBER is