Dun and Bradstreet. It is a nine-digit identification number, which provides unique identifiers of single business entities. The D–U–N–S number can be obtained from: https://iupdata.dnb.com/iUpdate/viewUpdateHome.htm.

4. Intergovernmental Review Executive Order 12372, Intergovernmental Review of Federal Programs, is not applicable to these grant applications.

IV. Submission Information
1. Application Kits
 Application kits/Program Instructions are available at www.grantsolutions.gov. Instructions for completing the application kit will be available on the site.

2. Submission Dates and Times
   To receive consideration, applications must be submitted by 11:59 p.m. Eastern time on August 14, 2017, through www.GrantSolutions.gov.

V. Agency Contacts
 Direct inquiries regarding programmatic issues to U.S. Department of Health and Human Services, Administration for Community Living, Office of Healthcare Information and Counseling, Washington, DC 20201, attention: Isaac C. Long or by calling 202–795–7315 or by email isaac.long@acl.hhs.gov.

[FR Doc. 2017–12339 Filed 6–13–17; 8:45 am]
BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2010–N–0622]

Agency Information Collection Activities; Proposed Collection; Comment Request; Color Additive Certification Requests and Recordkeeping

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (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 information collection provisions of FDA’s regulations governing batch certification of color additives manufactured for use in foods, drugs, cosmetics, or medical devices in the United States.

DATES: Submit either electronic or written comments on the collection of information by August 14, 2017.

ADDRESSES: You may submit comments as follows. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 14, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of August 14, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
   • For written/paper comments submitted to the Division of Dockets Management, 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–2010–N–0622 for “Agency Information Collection Activities; Proposed Collection; Comment Request; Color Additive Certification Requests and Recordkeeping.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at https://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on https://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to https://www.regulations.gov and insert the docket number, found in brackets in the
FOR FURTHER INFORMATION CONTACT:
JonnaLynn Capezzuto, FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794.

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; and (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.

Color Additive Certification Requests and Recordkeeping—21 CFR Part 80—OMB Control Number 0910–0216—Extension

We have regulatory oversight for color additives used in foods, drugs, cosmetics, and medical devices. Section 721(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(a)) provides that a color additive shall be deemed to be unsafe unless it meets the requirements of a listing regulation, including any requirement for batch certification, and is used in accordance with the regulation. We list color additives that have been shown to be safe for their intended uses in Title 21 of the Code of Federal Regulations (CFR). We require batch certification for all color additives listed in 21 CFR part 74 and for all color additives provisionally listed in 21 CFR part 82. Color additives listed in 21 CFR part 73 are exempted from certification.

The requirements for color additive certification are described in 21 CFR part 80. In the certification procedure, a representative sample of a new batch of color additive, accompanied by a “request for certification” that provides information about the batch, must be submitted to FDA’s Office of Cosmetics and Colors. FDA personnel perform chemical and other analyses of the representative sample and, providing the sample satisfies all certification requirements, issue a certificate. The requirements of its listing regulation.

Until at least 2 years after disposal of all of the color additive covered by the certificate. Such records are to be made available upon request by any accredited representative of FDA until at least 2 years after disposal of all of the color additive.

The purpose for collecting this information is to help us assure that only safe color additives will be used in foods, drugs, cosmetics, and medical devices sold in the United States. The required information is unique to the batch of color additive that is the subject of a request for certification. The manufacturer’s batch number is used for temporarily identifying a batch of color additive until FDA issues a certification lot number and for identifying a certified batch during inspections. The manufacturer’s batch number also aids in tracing the disposal of a certified batch or a batch that has been denied certification for noncompliance with the color additive regulations. The manufacturer’s batch weight is used for assessing the certification fee. The batch weight also is used to account for the disposal of a batch of certified or certification-denied color additive. The batch weight can be used in a recall to determine whether all unused color additive in the batch has been recalled. The manufacturer’s name and address and the number and address of the person requesting certification are to be made available upon request to any accredited representative of FDA.

We estimate the burden of this collection of information as follows:
We base our estimate on our review of the certification requests received over the past 3 fiscal years (FY). The annual burden estimate for this information collection is 3,536 hours. The estimated reporting burden for this information collection is 1,655 hours and the estimated recordkeeping burden for this information collection is 1,881 hours. From FY 2014 to FY 2016, we processed an average of 7,524 responses (requests for certification of batches of color additives) per year. There were 38 different respondents, corresponding to an average of approximately 198 responses from each respondent per year. Using information from industry personnel, we estimate that an average of 0.22 hour per response is required for reporting (preparing certification requests and accompanying samples) and an average of 0.25 hour per response is required for recordkeeping.

Our Web-based Color Certification information system allows submitters to request color certification online, follow their submissions through the process, and obtain information on account status. The system sends back the certification results electronically, allowing submitters to sell their certified color before receiving hardcopy certificates. Any delays in the system result only from shipment of color additive samples to FDA’s Office of Cosmetics and Colors for analysis.

### Table 1—Estimated Annual Reporting Burden 1

<table>
<thead>
<tr>
<th>21 CFR section/activity</th>
<th>Number of respondents</th>
<th>Number of responses per respondent</th>
<th>Total annual responses</th>
<th>Average burden per response</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>80.21; Request for Certification</td>
<td>38</td>
<td>198</td>
<td>7,524</td>
<td>0.17 (10 minutes)</td>
<td>1,279</td>
</tr>
<tr>
<td>80.22; Sample to Accompany Request</td>
<td>38</td>
<td>198</td>
<td>7,524</td>
<td>0.05 (3 minutes)</td>
<td>376</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td><strong>7,524</strong></td>
<td><strong>0.22 (13 minutes)</strong></td>
<td><strong>1,655</strong></td>
</tr>
</tbody>
</table>

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

### Table 2—Estimated Annual Recordkeeping Burden 1

<table>
<thead>
<tr>
<th>21 CFR section/activity</th>
<th>Number of recordkeepers</th>
<th>Number of records per recordkeeper</th>
<th>Total annual records</th>
<th>Average burden per recordkeeping</th>
<th>Total hours</th>
</tr>
</thead>
<tbody>
<tr>
<td>80.39; Record of Distribution</td>
<td>38</td>
<td>198</td>
<td>7,524</td>
<td>.25 (15 minutes)</td>
<td>1,881</td>
</tr>
</tbody>
</table>

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–E–2370]

Determination of Regulatory Review Period for Purposes of Patent Extension; HETLIOZ

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for HETLIOZ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (in the SUPPLEMENTARY INFORMATION section) are incorrect may submit either electronic or written comments and ask for a redetermination by August 14, 2017. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by December 11, 2017. See “Petitions” in the SUPPLEMENTARY INFORMATION section for more information.

ADDRESSES: You may submit comments as follows: Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before August 14, 2017. The https://www.regulations.gov electronic filing system will accept comments until midnight Eastern Time at the end of August 14, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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