

collection of information to OMB for review and clearance.

**Animal Food Labeling; Declaration of Certifiable Color Additives**

OMB Control Number 0910-0721—  
Extension

This information collection is associated with requirements under § 501.22(k) (21 CFR 501.22(k)) in which animal food manufacturers must declare the presence of certified and noncertified color additives in their animal food products on the product label. We issued this regulation in response to the Nutrition Labeling and Education Act of 1990 (Pub. L. 101-535) to make animal food regulations consistent with the regulations regarding the declaration of color additives on human food labels and to provide animal owners with information on the color additives used in animal food. Animal owners use the information to become knowledgeable

about the foods they purchase for their animals. Color additive information enables a consumer to comparison shop and to avoid substances to which their animals may be sensitive.

*Description of Respondents:*  
Respondents to this collection of information are manufacturers of pet food products that contain color additives. In the **Federal Register** of February 20, 2018 (83 FR 7198), FDA published a 60-day notice requesting public comment on the proposed collection of information.

(Comment) One comment was received that supported FDA’s need for the information collection and characterized the burden of the information collection as low compared to the importance of informative food labels. The comment did not suggest revising our estimate of the burden. However, it suggested we should provide greater detail about how we estimated the number of respondents and the flow of new products.

(Response) We based our estimate of the number of respondents on the number of pet food manufacturers subject to this regulation. The figure of 3,120 used in table 1 was derived from the number of establishments listed under North American Industrial Classification System codes 311111 and 311119, including very small establishments. As noted in the 60-day notice, we based our estimate of the flow of new products on A.C. Nielsen data for the number of animal food product units for sale (for which sales of the products are greater than zero) in the latest year for which data is available, stated to be 25,874. Then, we assumed that the flow of new products would be 10 percent per year, for a figure of 2,587 new products per year. That figure was used in table 1 as our estimate of the total annual disclosures. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN <sup>1</sup>

21 CFR Section/activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
501.22(k); labeling of color additive or lake of color additive; labeling of color additives not subject to certification.	3,120	0.8292	2,587	0.25 (15 minutes) .....	647

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

The requirement became effective November 18, 2013; thus, we estimate that the burden associated with the labeling requirements under § 501.22(k) applies only to new product labels. Because the vast majority of animal food products that contain certified color additives are pet foods, we limit our burden estimate to reviewing labels for the use of certified color additives to pet food manufacturers subject to this regulation. Based on A.C. Nielsen data, we estimate that the number of animal food product units subject to § 501.22(k) for which sales of the products are greater than zero is 25,874. Assuming that the flow of new products is 10 percent per year, then 2,587 new animal food products subject to § 501.22(k) will become available on the market each year. We also estimate that there are approximately 3,120 manufacturers of pet food subject to either § 501.22(k)(1) or (2). Assuming the approximately 2,587 new products are split equally among the firms, then each firm would prepare labels for approximately 0.8292 new products per year (2,587 new products—3,120 firms is approximately 0.8292 labels per firm). We expect that

firms prepare the required labeling for their products in a manner that takes into account at one time all information required to be disclosed on their product labels. Based on our experience with reviewing pet food labeling, we estimate that firms would require less than 0.25 hour (15 minutes) per product to comply with the requirement to include the color additive information pursuant to § 501.22(k). The total burden of this activity is 647 hours (2,587 labels × 0.25 hour/label is approximately 647 hours). The burden for this information collection has not changed since the last OMB approval.

Dated: June 26, 2018.  
**Leslie Kux,**  
Associate Commissioner for Policy.  
[FR Doc. 2018-14059 Filed 6-28-18; 8:45 am]  
**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2018-N-2398]

**Development of Non-Traditional Therapies for Bacterial Infections; Public Workshop; Request for Comments**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled “Development of Non-Traditional Therapies for Bacterial Infections.” The purpose of the public workshop is to discuss the general development considerations of non-traditional therapies, including pre-clinical development, early clinical studies, and phase 3 clinical trial designs to evaluate safety and efficacy.

**DATES:** The public workshop will be held on August 21, 2018, from 8:30 a.m. to 4:30 p.m. and August 22, 2018, from

8:30 a.m. to 12 noon. Submit either electronic or written comments on this public workshop by August 15, 2018. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

**ADDRESSES:** The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

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 15, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight eastern time on August 15, 2018. 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):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2018-N-2398 for "Development of Non-Traditional Therapies for Bacterial Infections; Public Workshop." 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 Dockets Management Staff 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 Dockets Management Staff. 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: <https://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 heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION CONTACT:** Lori Benner and/or Jessica Barnes, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6221, Silver Spring, MD 20993-0002, 301-796-1300.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing a public workshop regarding development of non-traditional therapies for bacterial infections. Discussions will focus on pre-clinical development, early stage clinical trials, and phase 3 clinical trial designs to evaluate safety and efficacy of non-traditional therapies intended to serve as primary or adjunctive therapy to existing antibacterial drugs.

##### II. Topics for Discussion at the Public Workshop

FDA is particularly interested in discussing pre-clinical and clinical development of several types of non-traditional therapies, including monoclonal antibodies, immunomodulators, lysins, and other non-traditional therapies.

The Agency encourages health care providers, other U.S. Government Agencies, academic experts, industry, and other stakeholders to attend this public workshop.

##### III. Participating in the Public Workshop

**Registration:** Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public workshop must register online by August 14, 2018, midnight Eastern Time. To register, please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone to [NonTraditionalTherapiesWorkshop2018@fda.hhs.gov](mailto:NonTraditionalTherapiesWorkshop2018@fda.hhs.gov).

Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 7:30 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Jessica Barnes or Lori Benner (see **FOR FURTHER INFORMATION CONTACT**) no later than August 13, 2018.

*Requests for Oral Presentations:* During online registration you may indicate if you wish to present during a public comment session or participate in a specific session, and which topic(s) you wish to address. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations or request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and notify participants by August 10, 2018. All requests to make oral presentations must be received by the close of registration on August 6, 2018. If selected for presentation, any presentation materials must be emailed to *NonTraditionalTherapiesWorkshop2018@fda.hhs.gov* no later than August 14, 2018. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

*Streaming Webcast of the Public Workshop:* This public workshop will also be webcast at the following site: <https://collaboration.fda.gov/dcontpfbi/>.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

*Transcripts:* Please be advised that as soon as a transcript of the public workshop is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A link to the transcript will also be available on the internet at <https://www.fda.gov/Drugs/NewsEvents/ucm606052.htm>.

Dated: June 26, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2017-D-6209]

#### Assessing User Fees Under the Biosimilar User Fee Amendments of 2017; Guidance for Industry; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled “Assessing User Fees Under the Biosimilar User Fee Amendments of 2017.” This guidance concerns FDA’s implementation of the Biosimilar User Fee Amendments of 2017 (BsUFA II) and certain changes in policies and procedures surrounding its application.

**DATES:** The announcement of the guidance is published in the **Federal Register** on June 29, 2018.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

#### *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):* Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2017-D-6209 for “Assessing User Fees Under the Biosimilar User Fee Amendments of 2017.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 Dockets Management Staff. 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: <https://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 heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management