

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

21 CFR part; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
§§ 101.3 and 101.22; statement of identity labeling requirements.	12	2	24	0.5 (30 minutes) .....	12
§ 101.4; ingredient labeling requirements .....	12	2	24	1 .....	24
§ 101.5; requirement to specify the name and place of business of the manufacturer, packer, or distributor.	12	2	24	0.25 (15 minutes) ...	6
§ 101.9; labeling requirements for disclosure of nutrition information.	12	2	24	4 .....	96
§ 101.7; declaration of net quantity of contents .....	12	2	24	0.5 (30 minutes) .....	12
Section 403(w)(1) of the FD&C Act; declaration of food allergens.	12	2	24	1 .....	24
Guidance document entitled “Labeling of Certain Beers Subject to the Labeling Jurisdiction of the Food and Drug Administration”.	12	1	12	1 .....	12
Total .....					186

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

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate. Our estimate of the number of respondents is based on the number of regulatory submissions to TTB for beers that do not meet the definition of a “malt beverage” under the FAA Act. Based on its records of submissions received from manufacturers of such products, TTB estimates the annual number of respondents to be 12 and the annual number of disclosures to be 24.

Our estimates of the average burden per disclosure for each collection provision are based on our experience with food labeling under the Agency’s jurisdiction. The estimated average burden per disclosure for §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.7 are equal to, and based upon, the estimated average burden per disclosure approved by OMB in OMB control number 0910–0381. We further estimate that the labeling burden of section 403(w)(1) of the FD&C Act, which specifies requirements for the declaration of food allergens, will be 1 hour based upon the similarity of the requirements to that of § 101.4. Finally, we estimate that a respondent will spend 1 hour reading the guidance.

The guidance also refers to previously approved collections of information found in our regulations. The collections of information in §§ 101.3, 101.4, 101.5, 101.9, 101.22, and 101.7 have been approved under OMB control number 0910–0381. Allergen labeling of these beers under section 403(w)(1) of the FD&C Act, which was added by the Food Allergen Labeling and Consumer Protection Act of 2004, has been

approved under OMB control number 0910–0792.

Dated: May 14, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–10750 Filed 5–20–21; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2019–D–3764]

#### **Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Containing Active Pharmaceutical Ingredients Considered To Be Soluble in Aqueous Media; Guidance for Industry; Availability**

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

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of a final guidance for industry (GFI) #171 entitled “Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Containing Active Pharmaceutical Ingredients Considered To Be Soluble in Aqueous Media.” This guidance describes how the Agency intends to evaluate requests for waiving the requirement for performing *in vivo* bioequivalence studies for animal drugs administered orally as soluble powders or as Type A medicated articles

manufactured from active pharmaceutical ingredients considered to be soluble in aqueous media.

**DATES:** The announcement of the guidance is published in the **Federal Register** on May 21, 2021.

**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-2019-D-3764 for “Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Containing Active Pharmaceutical Ingredients Considered To Be Soluble in Aqueous Media.” 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, 240-402-7500.

- **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.govinfo.gov/content/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, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

#### FOR FURTHER INFORMATION CONTACT:

- **Biopharmaceutics and Pharmacokinetics:** Marilyn Martinez, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0635, [Marilyn.Martinez@fda.hhs.gov](mailto:Marilyn.Martinez@fda.hhs.gov).

- **Manufacturing Chemistry:** Catherine Finnegan, Center for Veterinary Medicine (HFV-147), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0650, [Catherine.Finnegan@fda.hhs.gov](mailto:Catherine.Finnegan@fda.hhs.gov).

- **Generic Drug Approval Requirements/Solubility Concerns:** Ian S. Hendricks, Center for Veterinary Medicine (HFV-172), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-0853, [Ian.Hendricks@fda.hhs.gov](mailto:Ian.Hendricks@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

### I. Background

In the **Federal Register** of September 30, 2019 (84 FR 51595), FDA published the notice of availability for a draft guidance entitled “Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Containing Active Pharmaceutical Ingredients Considered to be Soluble in Aqueous Media” giving interested persons until November 29, 2019, to comment on the draft guidance. This guidance describes how the Agency intends to evaluate requests for waiving the requirement for performing *in vivo* bioequivalence studies (biowaivers) for animal drugs administered orally as soluble powders or as Type A medicated articles manufactured from active

pharmaceutical ingredients (APIs) considered to be soluble in aqueous media (water-soluble APIs). This guidance expands upon GFI #35, “Bioequivalence Guidance,” published November 8, 2006, to include biowaivers for soluble powder oral dosage form products as well as Type A medicated articles manufactured from APIs considered to be soluble in aqueous media. This guidance offers particular focus on criteria for the waiver of the requirements for submitting *in vivo* bioequivalence study data.

This guidance is applicable to generic investigational new animal drug (JINAD) files and to abbreviated new animal drug applications (ANADAs). Although the recommendations in this guidance refer to generic drug applications, the general principles described may also be applicable to new animal drug applications (NADAs), investigational new animal drug (INAD) files, and supplemental NADAs. This guidance does not address Type A medicated articles manufactured from APIs considered to be insoluble in aqueous media.

FDA received no comments on the draft guidance. The Agency made a minor change to the title of the guidance and other minor editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated September 30, 2019.

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on “Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products and Type A Medicated Articles Containing Active Pharmaceutical Ingredients Considered To Be Soluble in Aqueous Media.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

### II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in section 512(n)(1) of the Federal Food, Drug, and Cosmetic Act

(21 U.S.C. 360b(n)(1)) have been approved under OMB control number 0910-0669.

### III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry> or <https://www.regulations.gov>.

Dated: May 17, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2021-N-0458]

#### Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

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

**ACTION:** Notice; establishment of a public docket; request for comments.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (the Committee). The general function of the Committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

**DATES:** The meeting will be held on June 10, 2021, from 8:30 a.m. to 3:40 p.m. ET.

**ADDRESSES:** Please note that due to the impact of this COVID-19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. The online web conference meeting will be available at the following link on the day of the meeting: <https://youtu.be/70Xhn3K9SIQ>.

FDA is establishing a docket for public comment on this meeting. The docket number is FDA-2021-N-0458. The docket will close on June 9, 2021. Submit either electronic or written comments on this public meeting by June 9, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before June 9, 2021.

The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 9, 2021. 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.

Comments received on or before June 3, 2021, will be provided to the committee. Comments received after June 3, 2021, and by June 9, 2021, will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications, submissions, or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments 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>.

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- 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-2021-N-0458 for "Vaccines and Related Biological Products; Notice of Meeting; Establishment of a Public Docket; Request for Comments." 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, 240-402-7500.

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**FOR FURTHER INFORMATION CONTACT:** Prabhakara Atreya or Kathleen Hayes, Center for Biologics Evaluation and Research, Food and Drug