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.

Labeling of Plant-Based Alternatives to Animal-Derived Foods: Draft Guidance for Industry

OMB Control Number 0910–0381—Revision

The draft guidance, once finalized, will provide recommendations on best practices for naming and labeling of certain plant-based alternative foods. Industry's use of these recommendations for naming and labeling plant-based alternative foods will help ensure consumers understand the nature of individual plant-based alternative foods, including differences among these products, and have the information they need to make informed purchasing decisions.

Standards of identity have not been established for plant-based alternative foods. As such, plant-based alternative foods are non-standardized foods and must be labeled with their common or usual name, or in the absence thereof, a statement of identity that accurately describes the food. See 21 CFR 101.3(b). Many plant-based alternative foods are novel foods and do not have common or usual names established by common usage. Currently, products appear to be identified in multiple ways, sometimes inconsistently across the category. Thus, the purpose of this guidance is to provide our recommendations on best practices for naming and labeling of certain plant-based foods that are marketed and sold as alternatives for animal-derived foods.

Description of respondents: Respondents to this information collection are manufacturers, packers, and distributors of plant-based alternative foods that are marketed and sold in the United States. Respondents are from the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED THIRD-PARTY DISCLOSURE BURDEN

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs [1] [2]
Labeling recommendations in ''Labeling of Plant-Based Alternatives to Animal-Derived Foods''	160	5	800	1	800	$1,231,200

[1] One-time relabeling costs.
[2] There are no operating and maintenance costs associated with this collection of information.

The estimates in table 1 are based on our experience with similar labeling programs. We estimate that each year 160 manufacturers will relabel their products following recommendations found in the draft guidance. We estimate that each manufacturer will relabel 5 products for 800 total annual disclosures (160 manufacturers × 5 labels). Each disclosure will take an estimated 1 hour to complete for an annual third-party disclosure burden of 800 hours (800 disclosures × 1 hour). We estimate that there will be an annual capital cost of $1,231,200 associated with relabeling. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time burden per respondent.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents, https://www.fda.gov/FoodGuidances,* or *https://www.regulations.gov.* Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31535 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–3067]

Recommendations To Reduce the Risk of Transmission of Disease Agents Associated With Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a final guidance for immediate implementation entitled ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' FDA is issuing this guidance to provide establishments making donor eligibility determinations with recommendations to reduce the risk of transmission of infections due to sepsis by HCT/Ps. This notice is being issued to respond to a public health safety concern and to address the urgent need for updated recommendations in making a donor eligibility determination when screening a donor for clinical evidence of sepsis and clinical signs to consider.

DATES: The announcement of the guidance is published in the **Federal Register** on January 7, 2025.

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–2024–D–3067 for ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' 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 Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive labels to assist that office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jessica Gillum, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a final guidance for immediate implementation entitled ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).''

FDA is issuing the guidance to provide establishments making donor eligibility determinations with recommendations to reduce the risk of transmission of disease agents associated with sepsis for donors of human cells, tissues, and cellular and tissue-based products. This guidance supersedes the information regarding sepsis in the August 2007 guidance entitled ''Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' The August 2007 guidance identified sepsis as a relevant communicable disease agent or disease under 21 CFR 1271.3(r)(2).

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of another guidance for immediate implementation entitled ''Recommendations To Reduce the Risk of Transmission of *Mycobacterium Tuberculosis* (Mtb) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' This guidance is being issued to assist establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products, with recommendations for screening donors for evidence of, and risk factors for, infection with Mtb, the organism that causes tuberculosis, which can be a cause of sepsis.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (§ 10.115(g)(2)). We made this determination because of the urgent need to update recommendations to industry for screening a donor for risk factors and conditions, and clinical and physical evidence, associated with the disease agents that cause sepsis. Although this guidance document is immediately in effect, it remains subject to comment in accordance with FDA's GGP regulation.

The guidance represents the current thinking of FDA on ''Recommendations To Reduce the Risk of Transmission of Disease Agents Associated with Sepsis by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps).'' 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. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR 1271 relating to HCT/Ps, including establishing and maintaining records, investigation and reporting of adverse actions and documentation of methods used in facilities related to HCT/Ps, which, includes but not limited to donor screening, donor testing, and labeling have been approved under OMB control number 0910–0543.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 27, 2024.

Kimberlee Trzeciak,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2024–31538 Filed 1–6–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–D–5376]

Type VII Veterinary Master File for Research and Development and Risk Reviews; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft guidance for industry (GFI) #260 entitled ''Type VII Veterinary Master File for Research and Development and Risk Reviews.'' This draft guidance, when finalized, will describe FDA's current thinking regarding the use of Type VII Veterinary Master Files (Type VII VMFs). Type VII VMFs are appropriate for research and development of animal cells, tissues, and cell- and tissue-based products (ACTPs), gene therapies, and heritable intentional genomic alterations (IGAs) in animals.

DATES: Submit either electronic or written comments on the draft guidance by March 10, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–2024–D–5376 for ''Type VII Veterinary Master File for Research and Development and Risk Reviews.'' 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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: Lynne Boxer, Center for Veterinary Medicine, Food and Drug