reports, and inform policy and program development that is responsive to the needs of victims.

The information collection captures information on participant demographics (*e.g.,* age, gender identity, race/ethnicity, country of origin), type of trafficking experienced (sex, labor, or both), types of services and benefits provided, along with aggregate information on the amount of money spent on each type of service provided, outreach activities conducted, subrecipients enrolled, and the types of trainings provided to relevant audiences. Minor updates have been made to performance indicators under this collection in consultation with existing grant recipients and stakeholders, to reduce respondent burden, strengthen client privacy and confidentiality, and to bring the collection into alignment with program requirements under the revised TVAP. Specifically, to reduce burden and strengthen client privacy and confidentiality, the following TVAP client-level indicators have been removed: Type of Intake, Date of Birth, Services Requested at Intake, Benefits Requested at Intake, Trafficker Relationship to Victim, and Employment Status at Case Closure. To reduce respondent burden, additional proposed outreach and subrecipient indicators have also been removed: Screening Tool Used During Outreach, Goal of Subrecipient Partnership, Type of Subrecipient Partnership; Services Provided by Subrecipient (In-House) and Services Provided by Subrecipient (by Referral) have been collapsed into one category: Services Provided By Subrecipient. To bring the collection into alignment with the revised TVAP requirements, outreach-specific indicators have been added, specifically: Number of Outreach Activities Conducted, Date of Outreach Activity, Outreach Settings, Target Population(s), Number of Victims Identified. The TVAP Spending Form was renamed to Categories of Assistance and categories have been simplified to reduce reporting burden.

Respondents: TVAP Grant Recipients and Clients of those programs, specifically the: TVAP (HHS–2022–ACF–IOAS–OTIP–ZV–0150), Aspire: Child Trafficking Victim Assistance Demonstration Program (HHS–2022–ACF–IOAS–OTIP–TV–0099), Victims of Human Trafficking Services and Outreach Program—Pacific Region Demonstration Program (VHT–SO Pacific) (HHS–2022–ACF–IOAS–OTIP–ZV–0038) and the Lighthouse: Services, Outreach, and Awareness for Labor Trafficking (Lighthouse) Demonstration Program (HHS–2022–ACF–IOAS–OTIP–ZV–0059).

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Client Characteristics and Program Entry	6600	1	0.75	4950	1650
Client Case Closure	6600	1	0.167	1102.2	367.4
Barriers to Service Delivery and Monitoring	386	4	0.167	257.85	85.95
Client Service Use and Delivery	6600	1	0.25	1650	550
Victim Outreach	386	4	0.3	463.2	154.4
Training	386	4	0.5	772	257.3
Subrecipient Enrollment	193	2	0.167	64.5	21.5
Categories of Assistance	193	1	0.5	96.5	32.2

Estimated Total Annual Burden Hours: 3118.75.

Authority: 22 U.S.C. 7105.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2022–22842 Filed 10–20–22; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–D–6528]

Refusal of Inspection by a Foreign Food Establishment or Foreign Government; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a final guidance for industry entitled ''Refusal of Inspection by a Foreign Food Establishment or Foreign Government.'' The guidance will provide information for foreign food establishments subject to our inspection, as well as foreign governments, on when we may consider that a foreign food establishment or a government of a foreign country has refused to permit an inspection by us as provided in the Federal Food, Drug, and Cosmetic Act (FD&C Act).

DATES: The announcement of the guidance is published in the **Federal Register** on October 21, 2022.

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–6528 for ''Refusal of Inspection by a Foreign Food Establishment or Foreign Government.'' 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.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.

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 Compliance Policy Staff/Office of Compliance, Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Yinqing Ma, Center for Food Safety and Applied Nutrition (HFS–605), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2479.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance for industry entitled ''Refusal of Inspection by a Foreign Food Establishment or Foreign Government.'' We are issuing this guidance consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on this topic. 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.

In the **Federal Register** of December 12, 2017 (82 FR 58410), we made available a draft guidance for industry entitled ''Refusal of Inspection by a Foreign Food Establishment or Foreign Government'' and gave interested parties an opportunity to submit comments by February 26, 2018, for us to consider before beginning work on the final version of the guidance. We received several comments on the draft guidance and have modified the final guidance where appropriate. Changes to the guidance include: provided additional information on FDA's inspection authority; clarified that the investigator will inform the owner, operator, or agent in charge of the establishment when they consider their action to be a refusal and will explain the consequences of the refusal; and clarified that the Agency will make the final decision regarding refusal and listing on Import Alert 99–32. In addition, we made editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated December 2017.

II. Electronic Access

Persons with access to the internet may obtain the guidance at either *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: October 17, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–22884 Filed 10–20–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA 2016–D–4460]

Multiple Endpoints in Clinical Trials; 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 ''Multiple Endpoints in Clinical Trials.'' This guidance provides sponsors and review staff with the Agency's thinking about the problems posed by multiple endpoints in the analysis and interpretation of study results and how these problems can be managed in clinical trials for human drugs, including drugs subject to licensing as biological products. This guidance finalizes the draft guidance of the same title issued on January 13, 2017.

DATES: The announcement of the guidance is published in the **Federal Register** on October 21, 2022.

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