Health and Human Services (HHS) to make grants for a national communication system, the NHTH, to assist victims of severe forms of trafficking in persons in communicating with service providers. The objectives of the NHTH are to:

1. Operate the NHTH's telephone, text services, chat services, and website via a coordinated national communications system available 24 hours a day;

2. Provide timely information and service referrals to victims of human trafficking;

3. Notify law enforcement and child welfare agencies of potential cases of human trafficking, as required by law and in other situations where appropriate;

4. Establish and maintain a comprehensive online directory of community-based service providers across the U.S. and its territories.

The NHTH grant recipient collects information about signalers (individuals who contact the hotline) and from signalers regarding potential human trafficking situations and potential victims. The NHTH grant recipient summarizes and reports this information to HHS in the aggregate. HHS uses this information to assess the extent to which the grant recipient fulfills required program activities and to:

- Continuously monitor and mitigate factors impacting NHTH operations;
- Disseminate insights to inform anti-trafficking strategies and policies; and
- Provide information to congress, other federal agencies, stakeholders, and the public on the aggregate outcomes of NHTH operations.

Respondents: Potential victims, representatives of governmental entities, law enforcement, first responders, members of the community, representatives of nongovernmental entities supporting individuals in the U.S. who may have been subjected to severe forms of trafficking in persons who utilize the NHTH as signalers.

Annual Burden Estimates

The estimated number of respondents has been decreased to reflect review of operational data reviewed from the past five years. The updated estimate is an average number of respondents over the next three years based on that most recent data. The estimated time per response remains consistent but overall total estimates are lower due to the reduction in estimated number of respondents.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
NHTH Performance Indicators	51,000	1	0.5	76,500	25,500
NHTH Grant Recipient	1	15	24.13	362	121
Estimated Total Annual Burden Hours					25,621

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 22 U.S.C. 7105

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2025–11797 Filed 6–25–25; 8:45 am]

BILLING CODE 4184–47–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–0176]

Unique Device Identifier Requirements for Combination Products; Draft Guidance for Industry and FDA Staff; 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 draft guidance for industry and FDA staff entitled ''Unique Device Identifier (UDI) Requirements for Combination Products.'' This draft guidance is intended to assist industry and FDA staff in understanding how FDA's unique device identifier (UDI) requirements apply to combination products with device constituent parts.

DATES: Submit either electronic or written comments on the draft guidance by September 24, 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–2025–D–0176 for ''Unique Device Identifier (UDI) Requirements for Combination Products.'' 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 draft guidance to the to the Office of Combination Products, Food and Drug Administration, Bldg. 32, Rm. 5129, 10903 New Hampshire Ave. Silver Spring, MD 20993. 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: Stephanie Shapley, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 32, Rm. 5129, Silver Spring, MD 20993–0002, 301–796–4836, *stephanie.shapley@fda.hhs.gov* or *combination@fda.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and FDA staff entitled ''Unique Device Identifier (UDI) Requirements for Combination Products.'' A combination product is comprised of two or more different types of products (*i.e.,* a combination of a drug, device, and/or biological product with one another). Each drug, device, and biological product included in a combination product is referred to as a ''constituent part'' of the combination product (see 21 CFR 3.2). The final rule entitled ''Unique Device Identification System'' (UDI Rule), establishing the unique device identification system, published on September 24, 2013 (78 FR 58786). The UDI Rule requires that the label and device package of every medical device bear a UDI, unless an exception or alternative applies (see 21 CFR 801.20).

This draft guidance is intended to assist industry and FDA staff in understanding how FDA's UDI requirements at 21 CFR part 801 subpart B and part 830 subpart E apply to combination products with device constituent parts. This draft guidance outlines the requirements, recommendations, and best practices for UDI labeling and for submission of information to the Global Unique Device Identification Database for such combination products. This draft guidance also provides some hypothetical examples to illustrate how UDI requirements can be met for combination products.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Unique Device Identifier (UDI) Requirements for Combination Products.'' 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.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Other Issues for Consideration

The draft guidance acknowledges that for some co-packaged combination products that properly bear a National Drug Code, labelers may be able to identify each device constituent part based on information captured in the product identifier and the combination product's quality system (*e.g.,* the device version or model number and device lot/batch for each device). FDA requests public comment on the statement in the draft guidance that FDA is considering what approach or approaches to take in these circumstances for types of device constituent parts in such combination products. See section III.B. of the draft guidance.

III. 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 part 801 subpart B and 21 CFR part 830 have been approved under OMB control number 0910–0485.

IV. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/combination-products/guidance-regulatory-information/combination-products-guidance-documents, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: June 23, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11806 Filed 6–25–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 064

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (FDA Recognized Consensus Standards). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 064'' (Recognition List Number: 064), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments on the notice at any time. These modifications to the list of recognized standards are applicable June 26, 2025.

ADDRESSES: You may submit comments on the current list of FDA Recognized Consensus Standards 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–2004–N–0451 for ''Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 064.'' 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. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 064.

• 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.

An electronic copy of Recognition List Number: 064 is available on the internet at *https://www.fda.gov/medical-devices/division-standards-and-conformity-assessment/federal-register-documents.* See section IV for electronic access to the searchable database for the current list of FDA-recognized consensus standards, including Recognition List Number: 064 modifications and other standards-related information. Submit written requests for a single hard copy of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 064'' to Terry Woods, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301–796–2503. Send one self-addressed adhesive label to assist that office in processing your request or fax your request to 301–847–8144.

FOR FURTHER INFORMATION CONTACT: Terry Woods, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Silver Spring, MD 20993, 301–796–2503, *CDRHStandardsStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360d). Amended section 514 of the FD&C Act allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device