Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biologic product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human biological products, the testing phase begins when the exemption to permit the clinical investigations of the biological product becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application the market the human biological product and continues until FDA grants permission to market the biological product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human biological product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human biologic product KISUNLA (donanemab- azbt). KISUNLA is indicated for the treatment of Alzheimer's disease. Treatment with KISUNLA should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials. Subsequent to this approval, the USPTO received a patent term restoration application for KISUNLA (U.S. Patent No. 8,679,498) from Eli Lilly and Company, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated March 17, 2025, FDA advised the USPTO that this human biological product had undergone a regulatory review period and that the approval of KISUNLA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for KISUNLA is 4,137 days. Of this time, 3,360 days occurred during the testing phase of the regulatory review period, while 777 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* March 7, 2013. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on March 7, 2013.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* May 18, 2022. The applicant claims September 3, 2021, as the date the biologics license application (BLA) for KISUNLA (BLA 761248) was initially submitted. However, FDA records indicate that BLA 761248 was submitted on May 18, 2022, when a complete application was received.

3. *The date the application was approved:* July 2, 2024. FDA has verified the applicant's claim that BLA 761248 was approved on July 2, 2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,827 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.)

Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: July 8, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–13044 Filed 7–11–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–1560]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requirements for reporting and recordkeeping, general and specific requirements, and the availability of sample electronic products for manufacturers and distributors of electronic products.

DATES: Either electronic or written comments on the collection of information must be submitted by September 12, 2025.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 12, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be

considered timely if they are received 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. [Insert docket number xxxxx] for Reporting and Recordkeeping for Electronic Products. 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.

- 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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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.

Electronic Products

OMB Control Number 0910–0025—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360ii through 360ss), FDA has the responsibility to protect the public from unnecessary exposure of radiation from electronic products. The regulations issued under these authorities are listed in Title 21 of the Code of Federal Regulations, chapter I, subchapter J, parts 1000 through 1050 (21 CFR parts 1000 through 1050).

Section 532 of the FD&C Act directs the Secretary of Health and Human Services (the Secretary), to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the FD&C Act authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products. Section 534(g) of the FD&C Act directs the Secretary to review and evaluate industry testing programs on a continuing basis; and section 535(e) and (f) of the FD&C Act directs the Secretary to immediately notify manufacturers of, and ensure correction of, radiation defects or noncompliance with performance standards. Section 537(b) of the FD&C Act contains the authority to require manufacturers of electronic products to establish and maintain records

(including testing records), make reports, and provide information to determine whether the manufacturer has acted in compliance.

The regulations under parts 1002 through 1010 specify reports to be provided by manufacturers and distributors to FDA and records to be maintained in the event of an investigation of a safety concern or a product recall. FDA conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050. FDA details product-specific performance standards that specify information to be supplied with the product or require specific reports. The information collections are either specifically called for in the FD&C Act or were developed to aid the Agency in performing its obligations under the FD&C Act. The data reported to FDA and the records maintained are used by FDA and the industry to make decisions and take actions that protect the public from radiation hazards presented by electronic products. This information refers to the identification of, location of, operational characteristics of, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

FDA uses the following forms to aid respondents in the submission of information for this information collection:

- Form FDA 2579 ''Report of Assembly of a Diagnostic X-Ray System''
- Form FDA 2767 ''Notice of Availability of Sample Electronic Product''
- Form FDA 2877 ''Declaration for Imported Electronic Products Subject to Radiation Control Standards''
- Form FDA 3626 ''A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components''
- Form FDA 3627 ''Diagnostic X-Ray CT Products Radiation Safety Report''
- Form FDA 3628 ''General Annual Report (Includes Medical, Analytical, and Industrial X-Ray Products Annual Report)''
- Form FDA 3629 ''Abbreviated Report''
- Form FDA 3630 ''Guide for Preparing Product Reports on Sunlamps and Sunlamp Products''
- Form FDA 3631 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamp Products''
- Form FDA 3632 ''Guide for Preparing Product Reports on Lasers and Products Containing Lasers''
- Form FDA 3633 ''General Variance Request''
- Form FDA 3634 ''Television Products Annual Report''
- Form FDA 3635 ''Laser Light Show Notification''
- Form FDA 3636 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products''
- Form FDA 3637 ''Laser Original Equipment Manufacturer (OEM) Report''
- Form FDA 3638 ''Guide for Filing Annual Reports for X-Ray Components and Systems''
- Form FDA 3639 ''Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40''
- Form FDA 3640 ''Reporting Guide for Laser Light Shows and Displays''
- Form FDA 3147 ''Application for a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device''
- Form FDA 3641 ''Cabinet X-Ray Annual Report''
- Form FDA 3642 ''General Correspondence''
- Form FDA 3643 ''Microwave Oven Products Annual Report''
- Form FDA 3644 ''Guide for Preparing Product Reports for Ultrasonic Therapy Products''
- Form FDA 3645 ''Guide for Preparing Annual Reports for Ultrasonic Therapy Products''
- Form FDA 3646 ''Mercury Vapor Lamp Products Radiation Safety Report''
- Form FDA 3647 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps''
- Form FDA 3649 ''Accidental Radiation Occurrence (ARO)''
- Form FDA 3649C Consumer Accidental Radiation Occurrence Report''
- Form FDA 3659 ''Reporting and Compliance Guide for Television Products''
- Form FDA 3660 ''Guidance for Preparing Reports on Radiation Safety of Microwave Ovens''
- Form FDA 3661 ''A Guide for the Submission of an Abbreviated Report on X-Ray Tables, Cradles, Film Changers, or Cassette Holders Intended for Diagnostic Use''
- Form FDA 3662 ''A Guide for the Submission of an Abbreviated Radiation Safety Report on Cephalometric Devices Intended for Diagnostic Use''
- Form FDA 3663 ''Abbreviated Reports on Radiation Safety for Microwave Products (Other than Microwave Ovens)''
- Form FDA 3801 ''Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet Lamps and Products Containing Such Lamps''

The respondents to this information collection are electronic product and x-ray manufacturers, importers, consumers, and assemblers. The burden estimates were derived by consultation with FDA and industry personnel, and are based on data collected from industry, including product report submissions. An evaluation of the type and scope of information requested was also used to derive some time estimates.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Product reports—1002.10(a)–(k)	3639—Cabinet x-ray 3632—Laser; 3640—Laser light show; 3630—Sunlamp; 3659—TV; 3660—Microwave oven; 3801—UV lamps.	1,686	2.2	3,709	24	89,021
Supplemental reports—1002.11(a)–(b).	.....	484	2.5	1,210	0.5 (30 minutes)	605
Abbreviated reports—1002.12	3629—General abbreviated report; 3646—Mercury vapor lamp products radiation safety report; 3663—Microwave products (non-oven).	80	1.8	144	5	720

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity/21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Annual reports—1002.13(a)–(b)	3628—General; 3634—TV; 3641—Cabinet x-ray; 3643—Microwave oven; 3636—Laser; 3631—Sunlamp.	2,344	1.3	3,047	18	54,850
Accidental radiation occurrence reports—1002.20.	3649—ARO	96	4	384	2	768
Accidental radiation occurrence reports—1002.20.	3649S—ARO Summary	4	4	16	10	160
Accidental radiation occurrence reports—1002.20.	3649C—Consumer ARO	10	1	10	0.25	3
Exemption requests—1002.50(a) and 1002.51.	3642—General correspondence	5	1.3	7	1	7
Product and sample information—1005.10.	2767—Sample product	10	1	10	0.1 (6 minutes)	1
Identification information and compliance status—1005.25.	2877—Imports declaration	14,506	67	971,902	0.2 (12 minutes)	194,380
Alternate means of certification—1010.2(d).		1	1	1	5	5
Variance—1010.4(b)	3633—General variance request; 3147—Laser show variance request; 3635—Laser show notification.	580	1.1	638	1.2	766
Exemption from performance standards—1010.5(c) and (d).		1	1	1	22	22
Alternate test procedures—1010.13		1	1	1	10	10
Microwave oven exemption from warning labels—1030.10(c)(6)(iv).		1	1	1	1	1
Laser products registration—1040.10(a)(3)(i).	3637—Original equipment manufacturer (OEM) report.	42	2.9	122	3	366
Total		19,851		981,203		341,685

[1] Numbers have been rounded.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturer test and distribution records—1002.30 and 1002.31(a)	2,129	1,650	351,2850	0.12 (7 minutes)	421,542
Dealer/distributor records—1002.40 and 1002.41	3,000	50	150,000	0.05 (3 minutes)	7,500
Information on diagnostic x-ray systems—1020.30(g)	50	1	50	0.5 (30 minutes)	25
Laser products distribution records—1040.10(a)(3)(ii)	121	1	121	1	121
Total	5,300		3,663,021		429,188

[1] Numbers have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Activity/21 CFR section	FDA form	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [1]
Technical and safety information for users—1002.3.		1	1	1	12	12
Dealer/distributor records—1002.40 and 1002.41		30	3	90	1	90
Television receiver critical component warning—1020.10(c)(4).		1	1	1	1	1
Cold cathode tubes—1020.20(c)(4)		1	1	1	1	1
Report of assembly of diagnostic x-ray components—1020.30(d), (d)(1), and (d)(2).	FDA 2579—Assembler report.	1,235	34	41,990	0.30 (18 minutes)	12,597
Information on diagnostic x-ray systems—1020.30(g).		6	1	6	55	330
Statement of maximum line current of x-ray systems—1020.30(g)(2).		6	1	6	10	60
Diagnostic x-ray system safety and technical information—1020.30(h)(1)–(h)(4).		6	1	6	200	1,200
Fluoroscopic x-ray system safety and technical information—1020.30(h)(5)–(h)(6) and 1020.32(a)(1), (g), and (j)(4).		5	1	5	25	125
CT equipment—1020.33(c)–(d), (g)(4), and (j)		5	1	5	150	750
Cabinet x-ray systems information—1020.40(c)(9)(i)–(c)(9)(ii).		6	1	6	40	240
Microwave oven radiation safety instructions—1030.10(c)(4).		1	1	1	20	20
Microwave oven safety information and instructions—1030.10(c)(5)(i)–(c)(5)(iv).		1	1	1	20	20
Microwave oven warning labels—1030.10(c)(6)(iii).		1	1	1	1	1

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN—Continued

Activity/21 CFR section	FDA form	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [1]
Laser products information—1040.10(h)(1)(i)–(h)(1)(vi).		2	1	2	20	40
Laser product service information—1040.10(h)(2)(i)–(h)(2)(ii).		2	1	2	20	40
Medical laser product instructions—1040.11(a)(2)		2	1	2	10	20
Sunlamp products instructions—1040.20		1	1	1	10	10
Mercury vapor lamp labeling—1040.30(c)(1)(ii)		1	1	1	1	1
Mercury vapor lamp permanently affixed labels—1040.30(c)(2).		1	1	1	1	1
Total		1,314		42,129		15,558

[1] Total hours have been rounded.

Our estimated burden for the information collection reflects an overall increase of 381,828 hours and a corresponding increase of 2,135,962 responses.

We attribute this adjustment to the addition of the new FDA Form 3649C to this collection and the adjustment to an increase in respondents in the number of submissions we received over the last few years.

Dated: July 8, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–13052 Filed 7–11–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–4366; FDA–2024–E–4368; FDA–2024–E–4369]

Determination of Regulatory Review Period for Purposes of Patent Extension; IMDELLTRA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for IMDELLTRA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by September 12, 2025. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by January 12, 2026. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 12, 2025. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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 Nos. FDA–2024–E–4366; FDA–2024–E–4368; and FDA–2024–E–4369 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; IMDELLTRA.'' 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.

- 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