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–2007–D–0369 for ''Product-Specific Guidance for Levonorgestrel; Intrauterine Device.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' will be publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff office 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.gpo.gov/fdsys/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 draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. 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.

FOR FURTHER INFORMATION CONTACT: Wendy Good, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4730, Silver Spring, MD 20993–0002, 301–796–5850.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific guidances available to the public on FDA's website at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs.*

As described in that guidance, FDA adopted this process to develop and disseminate product-specific guidances and to provide a meaningful opportunity for the public to consider and comment on the guidances. This notice announces the availability of a revised draft guidance on a generic levonorgestrel intrauterine device.

FDA initially approved new drug application 21225 for MIRENA (levonorgestrel intrauterine device) in December 2000. In April 2014, FDA issued a draft product-specific guidance for industry on a generic levonorgestrel intrauterine device. FDA subsequently withdrew that draft guidance in October 2014 because the recommended in vitro studies lacked adequate specificity. We are now issuing a revised draft guidance for industry on a generic levonorgestrel intrauterine device (''Draft Guidance on Levonorgestrel'') with recommendations for a combination of two studies, in vitro testing and an in vivo/ex vivo study, to demonstrate BE.

In December 2015, Bayer HealthCare LLC, manufacturer of the reference listed drug MIRENA, submitted a citizen petition requesting that FDA withhold approval of any ANDA for a generic version of MIRENA unless certain conditions were satisfied, including conditions related to demonstrating BE ((Docket No. FDA–2015–P–4600), available at *https://www.regulations.gov*). FDA is reviewing the issues raised in that petition. However, FDA will consider any comments received on the guidance entitled, ''Draft Guidance on Levonorgestrel,'' before responding to the citizen petition.

The revised draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The revised draft guidance, when finalized, will represent the current thinking of FDA on the design of BE studies to support ANDAs for a levonorgestrel intrauterine device. 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. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: January 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01072 Filed 1–22–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0618]

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: Submit either electronic or written comments on the collection of information by March 23, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 23, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 23, 2020. 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.

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–2013–N–0618 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; 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.

- 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.

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—21 CFR Parts 1000 Through 1050

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 3649 ''Accidental Radiation Occurrence (ARO)''
- 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 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, 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 [2]
Product reports—1002.10(a) through (k).	3626—Diagnostic x-ray, 3627—CT x-ray, 3639—Cabinet x-ray, 3632—Laser, 3640—Laser light show, 3630—Sunlamp, 3646—Mercury vapor lamp, 3644—Ultrasonic therapy, 3659—TV, 3660—Microwave oven, 3801—UV lamps.	1,400	2.2	3,080	24	73,920
Product safety or testing changes—1002.11(a) and (b).	.....	480	2.5	1,200	0.5	600
Abbreviated reports—1002.12	3629—General abbreviated report, 3661—X-ray tables, etc., 3662—Cephalometric device, 3663—Microwave products (non-oven).	60	1.8	108	5	540
Annual reports—1002.13(a) and (b) ...	3628—General, 3634—TV, 3638—Diagnostic x-ray, 3641—Cabinet x-ray, 3643—Microwave oven, 3636—Laser, 3631—Sunlamp, 3647—Mercury vapor lamp, 3645—Ultrasonic therapy.	1,660	1.3	2,158	18	38,844
Quarterly updates for new models—1002.13(c).	.....	120	1.4	168	0.5	84
Accidental radiation occurrence reports—1002.20.	3649—ARO	30	6.7	201	2	402
Exemption requests—1002.50(a) and 1002.51.	3642—General correspondence	4	1.3	5	1	5
Product and sample information—1005.10.	2767—Sample product	5	1	5	0.1	1
Identification information and compliance status—1005.25.	2877—Imports declaration	12,620	2.5	31,550	0.2	6,310
Alternate means of certification—1010.2(d).	.....	1	2	2	5	10
Variance—1010.4(b)	3633—General variance request, 3147—Laser show variance request, 3635—Laser show notification.	350	1.1	385	1.2	462
Exemption from performance standards—1010.5(c) and (d).	.....	1	1	1	22	22
Alternate test procedures—1010.13	.....	1	1	1	10	10
Report of assembly of diagnostic x-ray components—1020.30(d), and (d)(1) and (2).	2579—Assembler report	1,230	34	41,820	0.30	12,546
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.	70	2.9	203	3	609
Total	.....	.....	.....	.....	.....	134,366

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours 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 [2]
Manufacturers records—1002.30 and 1002.31(a)	1,650	1,650	2,722,500	0.12	326,700
Dealer/distributor records—1002.40 and 1002.41	3,110	50	155,500	0.05	7,775
Information on diagnostic x-ray systems—1020.30(g)	50	1	50	0.5	25
Laser products distribution records—1040.10(a)(3)(ii)	70	1	70	1	70
Total	.....	.....	.....	.....	334,570

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
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

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
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
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) through (4)	6	1	6	200	1,200
Fluoroscopic x-ray system safety and technical information—1020.30(h)(5) and (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) and (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) through (iv)	1	1	1	20	20
Microwave oven warning labels—1030.10(c)(6)(iii)	1	1	1	1	1
Laser products information—1040.10(h)(1)(i) through (vi)	3	1	3	20	60
Laser product service information—1040.10(h)(2)(i) and (ii)	3	1	3	20	60
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
Ultrasonic therapy products—1050.10(d)(1) through (d), (f)(1), and (f)(2)(iii)	1	1	1	56	56
Total					3,058

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

Based on a review of the information collection, we have made no adjustments to our burden estimate.

Dated: January 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01073 Filed 1–22–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0145]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated With Animal Drug and Animal Generic Drug User Fees

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 the information collection provisions of FDA's animal drug and animal generic drug user fee programs.

DATES: Submit either electronic or written comments on the collection of information by March 23, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 23, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 23, 2020. 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.

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'').