on May 20, 2021 (86 FR 27447). This notice announces draft product-specific guidances, either new or revised, that are posted on FDA's website.

## II. Drug Products for Which New Draft Product-Specific Guidances Are Available

FDA is announcing the availability of new draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 1—NEW DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

| Active ingredient(s) |
|---|
| Acyclovir |
| Albuterol sulfate; Ipratropium bromide |
| Amisulpride |
| Avapritinib |
| Carbinoxamine maleate |
| Cefiderocol sulfate tosylate |
| Copper dotatate Cu-64 |
| Esomeprazole magnesium |
| Estradiol |
| Ethinyl estradiol; Levonorgestrel |
| Fostemsavir tromethamine |
| Indomethacin |
| Ipratropium bromide |
| Lasmiditan succinate |
| Leuprolide acetate |
| Loteprednol etabonate |
| Olodaterol hydrochloride |
| Osilodrostat phosphate |
| Ozanimod hydrochloride |
| Paliperidone palmitate |
| Semaglutide |
| Sufentanil citrate |
| Tazemetostat hydrobromide |

## III. Drug Products for Which Revised Draft Product-Specific Guidances Are Available

FDA is announcing the availability of revised draft product-specific guidances for industry for drug products containing the following active ingredients:

TABLE 2—REVISED DRAFT PRODUCT-SPECIFIC GUIDANCES FOR DRUG PRODUCTS

| Active ingredient(s) |
|---|
| Bexarotene |
| Budesonide |
| Eltrombopaq olamine (multiple referenced listed drugs) |
| Ferric citrate |
| Letrozole |
| Leuprolide acetate (multiple referenced listed drugs) |
| Liothyronine sodium |
| Loteprednol etabonate |
| Nystatin |
| Orlistat |
| Paclitaxel |
| Podofilox |
| Sodium zirconium cyclosilicate |
| Tazarotene |

For a complete history of previously published **Federal Register** notices related to product-specific guidances, go to *https://www.regulations.gov* and enter Docket No. FDA–2007–D–0369.

These draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized, will represent the current thinking of FDA on, among other things, the product-specific design of BE studies to support ANDAs. They do not establish any rights for any person and are not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that these draft guidances contain no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

## V. Electronic Access

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

Dated: August 18, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–18072 Filed 8–20–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2021–N–0359]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by September 22, 2021.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0858. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

### Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act

*OMB Control Number 0910–0858—Revision*

This information collection supports implementation of sections 503A and 503B of the Federal Food, Drug, and

Cosmetic Act (FD&C Act) (21 U.S.C. 353a and 21 U.S.C. 353b), which govern compounding by pharmacies, outsourcing facilities, and other entities. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients, they also present risks to patients. Our compounding program aims to protect patients from unsafe, ineffective, and poor quality compounded drugs, while preserving access to lawfully-marketed compounded drugs for patients who have a medical need for them. Respondents to the information collection are pharmacies, outsourcing facilities, and other entities.

To assist respondents in complying with statutory requirements, we have issued the following topic-specific guidance documents:

TABLE 1—PUBLISHED GUIDANCE DOCUMENTS REGARDING SECTIONS 503A AND 503B OF THE FD&C ACT

| Title | Notice of availability publication date |
|---|---|
| Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities (''*Radiopharmaceutical Compounding and Repackaging Guidance*''). | September 26, 2018 (83 FR 48633). |
| Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities (''*Radiopharmaceutical Outsourcing Repackaging Guidance*''). | September 26, 2018 (83 FR 48630). |
| Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities (''*Repackaging Guidance*''). | January 13, 2017 (82 FR 4343). |
| Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application (''*Biologics Guidance*''). | January 19, 2018 (83 FR 2787). |

These guidance documents were issued consistent with our Good Guidance Practice regulations in 21 CFR part 10.115 which provide for public comment at any time. The guidance documents communicate our current thinking on the respective topics and include information collection that may result in expenditures of time and effort by respondents. In our notices of availability we also solicited public comment under the PRA on the information collection provisions. FDA has developed and maintains a searchable guidance database available at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents.* Guidance documents covered by this information collection may be found by choosing ''Center for Drug Evaluation and Research'' from among the FDA Organizations, and by selecting the term ''Compounding'' from among the possible ''Topic'' filters.[1] For efficiency of operations we are consolidating the related information collections.

**Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities**

Because Congress explicitly excluded radiopharmaceuticals from section 503A of the FD&C Act (see section 503A(d)(2)), compounded radiopharmaceuticals are not eligible for the exemptions under section 503A from section 505 of the FD&C Act (21 U.S.C. 355) (concerning new drug approval requirements), section 502(f)(1) of the FD&C Act (21 U.S.C. 352(f)(1)) (concerning labeling with adequate directions for use), and section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)B)) (concerning current good manufacturing practice (CGMP) requirements). In addition, the FD&C Act does not provide an exemption for repackaged radiopharmaceuticals. This guidance document describes the conditions under which FDA does not intend to take action for violations of sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act when a state-licensed nuclear pharmacy, Federal facility, or other facility that is not an outsourcing facility and that holds a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State compounds or repackages radiopharmaceuticals for human use. The guidance explains that one condition is that the compounded radiopharmaceutical is not essentially a copy of an approved radiopharmaceutical. As described in the guidance, FDA does not intend to consider a compounded radiopharmaceutical to be essentially a copy if, among other reasons, there is a change between the compounded radiopharmaceutical and the approved radiopharmaceutical that produces a clinical difference for an identified individual patient, as determined by the prescribing practitioner and documented in writing on the prescription or order. In addition, FDA does not intend to consider a compounded radiopharmaceutical to be essentially a copy if the FDA-approved radiopharmaceutical is on FDA's drug shortage list (see section 506E of the FD&C Act (21 U.S.C. 356e)) at the time of compounding and distribution. If the facility compounded a drug that is identical or nearly identical to an approved drug product that appeared on FDA's drug shortage list, the facility should maintain documentation (*e.g.,* a notation on the order for the compounded drug) regarding the status of the drug on FDA's drug shortage list at the time of compounding, distribution, and dispensing.

**Radiopharmaceutical Outsourcing Repackaging Guidance**

In contrast to section 503A, section 503B of the FD&C Act does not exclude radiopharmaceuticals. Therefore, FDA's overall policies regarding section 503B apply to the compounding of radiopharmaceutical drug products. However, we have developed specific policies that apply only to the compounding of radiopharmaceuticals by outsourcing facilities using bulk drug substances and to the compounding of radiopharmaceuticals by outsourcing facilities that are essentially copies of approved drugs when such compounding is limited to minor deviations, as that term is defined in the guidance. FDA issued this guidance in part to describe the conditions under which the Agency does not generally intend to take action for violations of sections 505 and 502(f)(1) of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals for human use.

[1] Guidance documents applicable to animal drug compounding regulated by our Center for Veterinary Medicine would also be returned if no FDA Organization is selected; this information collection covers only those Compounding documents issued by the Center for Drug Evaluation and Research.

As discussed in the guidance, one condition is that if a radiopharmaceutical is repackaged by an outsourcing facility, the label on the immediate container (primary packaging, *e.g.,* the syringe) of the repackaged product includes certain information. The guidance also provides that the label on the container from which the individual units are removed for administration (secondary packaging, *e.g.,* the bag, box, or other package in which the repackaged products are distributed) includes: (1) The active and inactive ingredients, if the immediate product label is too small to include this information, and directions for use, including (as appropriate) dosage and administration and (2) the following information to facilitate adverse event reporting: and 1–800–FDA–1088.

**Repackaging Guidance**

This guidance describes the conditions under which FDA does not intend to take action for violations of sections 505 (concerning new drug applications), 502(f)(1) (concerning labeling with adequate directions for use), 582 ((21 U.S.C. 360eee–1) concerning drug supply chain security requirements), and (where specified in the guidance) section 501(a)(2)(B) of the FD&C Act (concerning CGMPs), when a state-licensed pharmacy, Federal facility, or outsourcing facility repackages certain prescription drug products. One condition discussed in the guidance is that if a drug is repackaged by an outsourcing facility, the label on the immediate container (primary packaging, *e.g.,* the syringe) of the repackaged product includes certain information described in the guidance.

Another condition discussed in the guidance is that the label on the container from which the individual units are removed for administration (secondary packaging, *e.g.,* the bag, box, or other package in which the repackaged products are distributed) includes: (1) The active and inactive ingredients, if the immediate product label is too small to include this information, and directions for use, including (as appropriate) dosage and administration, (2) directions for use, including, as appropriate, dosage and administration, and (3) the following information to facilitate adverse event reporting: *https://www.fda.gov/medwatch* and 1–800–FDA–1088.

**Biologics Guidance**

Certain licensed biological products may sometimes be mixed, diluted, or repackaged in a way not described in the approved labeling for the product to meet the needs of a specific patient. As described in the guidance, biological products subject to licensure under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262) are not eligible for the statutory exemptions available to certain compounded drugs under sections 503A and 503B of the FD&C Act. In addition, a biological product that is mixed, diluted, or repackaged outside the scope of an approved Biologics License Application (BLA) is considered an unlicensed biological product under section 351 of the PHS Act.

This guidance document describes several conditions under which FDA does not intend to take action for violations of section 351 of the PHS Act and sections 502(f)(1), 582, and (where specified) 501(a)(2)(B) of the FD&C Act, when a State-licensed pharmacy, a Federal facility, or an outsourcing facility dilutes, mixes, or repackages certain biological products outside the scope of an approved BLA.

One condition discussed in the guidance is that if the labeling for the licensed biological product includes storage instructions, handling instructions, or both (for example, protect from light, do not freeze, keep at specified storage temperature), the labeling for the biological product that is mixed, diluted, or repackaged specifies the same storage conditions. Another condition described in the guidance is that, if the biological product is mixed, diluted, or repackaged by an outsourcing facility, the label on the immediate container (primary packaging, for example, the syringe) of the mixed, diluted, or repackaged product includes certain information described in the guidance. In addition, the guidance communicates that as a condition for biological products mixed, diluted, or repackaged by an outsourcing facility that, if the immediate product label is too small to bear the active and inactive ingredients, such information is included on the label of the container from which the individual units are removed for administration (secondary packaging, for example, the bag, box, or other package in which the mixed, diluted, or repackaged biological products are distributed).

The guidance also communicates our thinking about the condition for biological products mixed, diluted, or repackaged by an outsourcing facility that the label on the container from which the individual units are removed for administration include directions for use. These directions include, as appropriate, the dosage and administration and the following information to facilitate adverse event reporting: *https://www.fda.gov/medwatch* and 1–800–FDA–1088.

Finally, another condition described in the guidance is that outsourcing facilities maintain records of the testing performed in accordance with ''Appendix A—Assigning a BUD for Repackaged Biological Products Based On Stability Testing'' of the guidance for biological products repackaged by outsourcing facilities for which the beyond use date (BUD) is established based on a stability program conducted in accordance with Appendix A.

Section III.C of the guidance, ''Licensed Allergenic Extracts for Subcutaneous Immunotherapy,'' discusses the preparation of prescription sets (that is, licensed allergenic extracts that are mixed and diluted to provide subcutaneous immunotherapy to an individual patient) by a physician, a State-licensed pharmacy, a Federal facility, or an outsourcing facility. Another condition described in the guidance is that if the prescription set is prepared by an outsourcing facility, the label of the container from which the individual units of the prescription set are removed for administration (secondary packaging) includes the following information to facilitate adverse event reporting: *https://www.fda.gov/medwatch* and 1–800–FDA–1088. Each prescription set prepared by an outsourcing facility is also accompanied by instructions for use.

In the **Federal Register** of April 29, 2021 (86 FR 22674), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

| Activity | Number of respondents | Number of disclosures per respondent | Total annual disclosures | Average burden per disclosure | Total hours |
|---|---|---|---|---|---|
| **Radiopharmaceutical Guidance** | | | | | |
| Consultation between the compounder and prescriber and the notation on the prescription or order documenting the prescriber's determination of clinical difference. | 10 | 25 | 250 | .05 (3 minutes). | 12.5 |
| **Radiopharmaceutical Outsourcing And Repackaging Guidance** | | | | | |
| Designing, testing, and producing each label on immediate containers, packages and/or outer containers. | 2 | 5 | 10 | 0.5 (30 minutes). | 5 |
| **Repackaging Guidance** | | | | | |
| Designing, testing, and producing each label on immediate containers, packages, and/or outer containers. | 6 | 21 | 126 | 1 | 126 |
| Biannual product reports identifying drug products repackaged by the outsourcing facility during the previous 6-month period (Guidance Section III.A.). | 3 | 4 | 12 | 3 | 24 |
| **Biologics Guidance** | | | | | |
| Designing, testing, and producing the label, container, packages, and/or outer containers for each mixed, diluted, or repackaged biological product. | 15 | 5 | 75 | 0.5 (30 minutes). | 37.5 |
| Designing, testing, and producing each label on immediate containers, packages and/or outer containers for each licensed allergenic extract. | 5 | 300 | 1,500 | 0.5 (30 minutes). | 750 |
| Maintaining records of testing performed in accordance with Biologics Guidance Appendix A. | 5 | 30 | 150 | 0.083 (5 minutes). | 12.5 |
| Total | | | 2,123 | | 967.5 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

As defined in 44 U.S.C. 3502(13), the term ''recordkeeping requirement'' means a requirement imposed on respondents to maintain specified records, as well as a requirement to ''retain such records; notify third parties, the Federal Government, or the public of the existence of such records; disclose such records to third parties, the Federal Government, or the public; or report to third parties, the Federal Government, or the public regarding such records.'' For purposes of our analysis, therefore, we have characterized the burden associated with the time and effort expended on the information collection recommendations discussed in the respective guidance documents as recordkeeping activities. At the same time, our findings show that compliance with recordkeeping requirements applicable to compounded and repackaged drug products is standard practice in the compounding and selling of these drug products under States' pharmacy laws and other State laws governing recordkeeping by healthcare professionals and healthcare facilities. We have therefore excluded from our estimate recordkeeping practices discussed in the respective guidance documents we consider usual and customary. We invite comment on this assumption.

**Radiopharmaceutical Compounding and Repackaging Guidance**

We estimate 10 compounders annually will consult a prescriber to determine whether a compounded radiopharmaceutical has a change that produces a clinical difference for an identified individual patient as compared to the comparable approved radiopharmaceutical. We estimate that those compounders will document this determination on 250 prescriptions or orders for compounded radiopharmaceuticals. We assume consultation between the compounder and the prescriber and noting this determination on each prescription or order that does not already document this determination will take 3 minutes (0.05 hours) per prescription or order, for a total of approximately 12.5 hours.

**Radiopharmaceutical Outsourcing and Repackaging Guidance**

We estimate a total of 2 outsourcing facilities annually will each design, test, and produce an average of 5 different labels for a total of 10 labels, as described in the guidance (including directions for use). We assume that designing, testing, and producing each label will take 30 minutes (0.5 hours) for each repackaged radiopharmaceutical, for a total of 5 hours. We consider that the provision to include ''*https://www.fda.gov/medwatch*'' and ''1–800–FDA–1088'' is not a collection of information as defined in 5 CFR 1320.3(c)(2) and is therefore exempt from OMB review and approval under the PRA.

**Repackaging Guidance**

Based on current data for outsourcing facilities, we estimate 6 outsourcing facilities annually will submit an initial report identifying all drugs repackaged in the facility in the previous year. For the purposes of this estimate, each product's structured product labeling (SPL) submission is considered a separate response and therefore each facility's product report will include multiple responses. Taking into account that a particular product that is repackaged may come in different strengths and can be reported in a single

SPL response, we estimate that each facility will average approximately 6 products.

Similarly, we estimate that 6 outsourcing facilities will submit an initial report identifying all drugs repackaged in the facility in the past year. Taking into account that a particular product that is repackaged may come in different strengths and can be reported in a single SPL response, we assume that each facility will average 6 products. Our estimate is based on current product reporting data. We expect that each product report will consist of multiple SPL responses per facility and assume preparing and electronically submitting this information will take up to 2 hours for each initial SPL response.

We also estimate 3 registered outsourcing facilities will submit a report twice each year (June and December) that identifies all drugs repackaged at the facility in the previous 6 months. We also estimate that an average of 3 facilities will prepare and submit 3 SPL responses and assume that preparing and submitting this information electronically could also take up to 2 hours per response. If a product was not repackaged during a particular reporting period, outsourcing facilities do not need to send an SPL response for that product during that reporting period. Our figures reflect what we believe to be the average burden among respondents. We expect to receive no waiver requests from the electronic submission process for initial product reports and semiannual reports.

**Biologics Guidance**

We estimate 15 outsourcing facilities annually who mix, dilute, or repackage biological products will each design, test, and produce 5 different labels, for a total of 75 labels that include the information set forth in section III.B—''Mixing, Diluting, or Repackaging Licensed Biological Products'' of the guidance (including directions for use) as well as inclusion of storage instructions, handling instructions, or both. We assume that designing, testing, and producing each label will take 30 minutes (0.5 hours). We consider that the provision to include ''*https://www.fda.gov/medwatch*'' and ''1–800–FDA–1088'' is not a collection of information as defined in 5 CFR 1320.3(c)(2) and is therefore exempt from OMB review and approval under the PRA.

We estimate that annually a total of 5 outsourcing facilities that prepare prescription sets will each include on the labels, packages, and/or containers of approximately 300 prescription sets the information set forth in section III.C ''Licensed Allergenic Extracts for Subcutaneous Immunotherapy'' of the draft guidance (including directions for use), for a total of 1,500 disclosures. We assume the initial process of designing, testing, and producing labeling and attaching to each prescription set each label, package, and/or container will take approximately 30 minutes (0.5 hours), for a total of approximately 750 hours.

Finally, we estimate that annually five outsourcing facilities who repackage biological products and establish a BUD in accordance with Appendix A—''Assigning a BUD for Repackaged Biological Products Based On Stability Testing'' will maintain 150 records of the testing, as described in Appendix A of the guidance. We assume maintaining the records will take 5 minutes per record, for a total of 12.5 hours.

Our estimated burden for the information collection reflects program changes and adjustments. We are changing the scope of the information collection to include burden attendant to provisions found in the Agency guidance documents discussed in this notice and have adjusted our estimate to reflect a resulting increase of 955 hours and 1,873 responses annually.

Dated: August 5, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

[FR Doc. 2021–17996 Filed 8–20–21; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–D–1464]**

### Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an Abbreviated New Drug Application; Draft 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 revised draft guidance for industry entitled ''Bioequivalence Studies With Pharmacokinetic Endpoints for Drugs Submitted Under an ANDA.'' This revised draft supersedes the draft guidance entitled ''Bioequivalence Studies With Pharmacokinetic Endpoints for Drug Products Submitted Under an ANDA,'' which was announced in the **Federal Register** on December 5, 2013. This revised draft guidance provides recommendations to applicants planning to include bioequivalence (BE) information in abbreviated new drug applications (ANDAs) and ANDA supplements. In addition, this guidance describes how to meet the BE requirements set forth in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations.

**DATES:** Submit either electronic or written comments on the draft guidance by October 22, 2021 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–