program, visit *https://www.adobe.com/go/connectpro_overview.* FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at *https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-cder-standard-core-sets-clinical-outcome-assessments-and-endpoints-grant-program.*

Dated: November 15, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25160 Filed 11–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4533]

Compounding Animal Drugs From Bulk Drug Substances; Draft Guidance for Industry; Availability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SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of draft guidance for industry (GFI) #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' The draft guidance, if finalized, will describe FDA's current thinking about compounding animal drugs from bulk drug substances. FDA has generally exercised enforcement discretion with regard to animal drug compounding from bulk drug substances under certain circumstances when no other medically appropriate treatment options exist. This draft guidance, a continuation of this practice, is intended to provide additional information and clarity to veterinarians and pharmacists about FDA's current thinking with respect to animal drug compounding from bulk drug substances. FDA previously published draft guidance on this issue for public comment in May 2015 (Draft GFI #230, ''Compounding Animal Drugs from Bulk Drug Substances''). We received over 150 comments on that draft guidance. Based on those comments, we decided to withdraw the May 2015 draft guidance and publish this draft guidance for public comment.

DATES: Submit either electronic or written comments on the draft guidance by February 18, 2020 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit either electronic or written comments on the proposed collection of information by February 18, 2020.

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–2018–D–4533 for ''Compounding Animal Drugs From Bulk Drug Substances.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.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 guidance to the Policy and Regulations Staff (HFV–6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. 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: *With regard to this draft guidance:* Eric

Nelson, Division of Compliance (HFV–230), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–7001, *cvmcompliance@fda.hhs.gov.*

With regard to the proposed collection of information: 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:

I. Background

FDA is announcing the availability of draft GFI #256 entitled ''Compounding Animal Drugs from Bulk Drug Substances.'' FDA has generally exercised enforcement discretion with regard to animal drug compounding from bulk drug substances under certain circumstances when no other medically appropriate treatment options exist. This draft guidance, a continuation of this practice, is intended to provide additional information and clarity to veterinarians and pharmacists about FDA's current thinking with respect to animal drug compounding from bulk drug substances. We previously announced the availability of a draft guidance addressing this issue (GFI #230, ''Compounding Animal Drugs from Bulk Drug Substances'') in the **Federal Register** of May 19, 2015 (80 FR 28624). In response to the comments received on GFI #230, we decided not to finalize that draft guidance, and instead are issuing draft GFI #256 for comment. If finalized, this draft guidance will describe the circumstances under which, based on our current understanding of the risks of animal drugs compounded from bulk drug substances, FDA does not intend to take enforcement action against pharmacies and veterinarians who compound animal drugs for violations of the FD&C Act's requirements for: (1) Approval; (2) adequate directions for use; and (3) current good manufacturing practices.

Elsewhere in this issue of the **Federal Register**, FDA is requesting nominations for bulk drug substances to be included on the ''List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals or Antidotes for Food-Producing Animals'' (the List) described in draft GFI #256. That **Federal Register** notice describes information needed by FDA to evaluate nominations and explains when FDA will include bulk drug substances on the List; such nominations will be collected in a separate docket. The List is available at *http://wcms.fda.gov/FDAgov/AnimalVeterinary/ComplianceEnforcement/UnapprovedAnimalDrugs/ucm596211.htm.*

II. Specific Topic for Comment

In addition to any other comments on the draft guidance, we are specifically requesting comments on section III.A.5 of the draft guidance. That section provides that if a compounded drug contains the same active moiety as a marketed FDA-approved, conditionally approved, or indexed animal drug or an FDA-approved human drug but as a different salt, ester, or other noncovalent derivative, there should be a difference between the compounded drug and the FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug that will produce a clinical difference in the patient and the medical rationale is documented in the prescription, or if a veterinarian is compounding the drug, the medical rationale is noted in the patient's medical record.

FDA is concerned that compounding an animal drug using a different salt, ester, or other noncovalent derivative of the same active moiety used in a marketed FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug can affect the absorption, distribution, metabolism, excretion, and stability of the compounded animal drug. All of these factors contribute to a drug's safety and effectiveness.

FDA is also concerned that compounding an animal drug from a different salt, ester, or other noncovalent derivative of the same active moiety as a marketed FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug may impact the incentives for seeking legal marketing status of a new animal drug (*i.e.,* approval, conditional approval, or indexing). Unlimited compounding using a different salt, ester, or other noncovalent derivative could cause a disincentive for new animal drug sponsors to continue to research and develop innovative new animal drugs.

However, FDA believes that in some cases the prescribing veterinarian may determine that a new animal drug from a different salt, ester, or other noncovalent derivative of the same active moiety as a marketed FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug will produce a clinical difference for the identified patient. Under the draft guidance, a pharmacy could compound such an animal drug if the prescribing veterinarian documents such a determination on the prescription, or if a veterinarian is compounding the drug, the medical rationale is noted in the patient's medical record.

FDA invites public comment on this issue.

III. Significance of Guidance

This Level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, if finalized, will represent the current thinking of FDA on compounding animal drugs from bulk drug substances. 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

IV. Paperwork Reduction Act of 1995

This draft guidance contains proposed information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3521). ''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** for each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, we are publishing this notice of the proposed collection of information set forth in this document.

With respect to the collection of information associated with this draft guidance, we invite 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 collected; and (4) ways to minimize the burden of the information collected on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Compounding Animal Drugs from Bulk Drug Substances (OMB Control Number 0910–NEW).

Description of Respondents: The proposed respondents are pharmacists

in either State-licensed pharmacies or Federal facilities, or veterinarians, who compound animal drugs from bulk drug substances.

Description: The Center for Veterinary Medicine has written draft GFI #256 to address a perceived need for Agency guidance in its work with the animal health industry. The draft guidance describes FDA's current thinking, based on our current understanding of the risks of animal drugs compounded from bulk drug substances, and describes the circumstances under which FDA does not intend to take enforcement action against pharmacists and veterinarians who compound animal drugs from bulk drug substances.

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

Reporting: The draft guidance contains no new reporting provisions.

Recordkeeping: The draft guidance contains a new recordkeeping provision. Our exercise of discretion is dependent upon our ability to assess whether the circumstances under which FDA would intend to exercise such discretion, as described in this draft guidance, exist. FDA staff may use pharmacy and veterinary records, among other things, to determine the circumstances surrounding the compounding activity. Except with regard to one proposed item, the routine business records kept by pharmacists who compound animal drugs from bulk drug substances and veterinarians who compound animal drugs from bulk drug substances, as well as veterinarians prescribing compounded animal drugs within a valid veterinarian-client-patient relationship, should be adequate to demonstrate that the circumstances described in the draft guidance exist.

The draft guidance sets forth circumstances for the compounding of animal drugs from bulk drug substances. Section III.A.4 of the draft guidance provides that if the compounded drug is a copy of a marketed FDA-approved, conditionally approved, or indexed animal drug or an FDA-approved human drug, there is a difference between the compounded drug and the FDA-approved, conditionally approved, or indexed animal drug or the FDA-approved human drug that will produce a clinical difference in the identified patient and the medical rationale is documented in the prescription, or if a veterinarian is compounding the drug, the medical rationale is noted in the patient's medical record. We tentatively conclude that it is usual and customary for veterinarians to document their medical rationale for using such a compounded product as a matter of maintaining an adequate medical record in routine practice; therefore, no burden has been estimated for the time it would take for a veterinarian to make this record.

Section III.A.5 of the draft guidance provides that if the compounded drug contains the same active moiety as a marketed FDA-approved, conditionally approved, or indexed animal drug or an FDA-approved human drug but as a different salt, ester, or other noncovalent derivative, there is a difference between the compounded drug and the marketed FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug that will produce a clinical difference in the identified patient. In such a case, the medical rationale is documented in the prescription, or if a veterinarian is compounding the drug, the medical rationale is noted in the patient's medical record. We tentatively conclude that it is usual and customary for veterinarians to document their medical rationale for using such a compounded product as a matter of maintaining an adequate medical record in routine practice; therefore, no burden has been estimated for the time it would take for a veterinarian to make this record.

Section III.A.6 of the draft guidance provides that if the compounded animal drug has any of the same active ingredient moiety(ies) as one or more marketed FDA-approved, conditionally approved, or indexed animal drugs or FDA-approved human drugs, the compounder has determined and documented the reason(s) why the FDA-approved, conditionally approved, or indexed animal drug(s) or FDA-approved human drug(s) cannot be used as the source of the active ingredient(s). We tentatively conclude that it is not usual and customary in routine business practice for a compounder to document that rationale; therefore, we estimate the time it would take for a compounder to make this record, as follows.

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Compounder recordkeeping to document the rationale (section III.A.6 of the draft guidance).	7,500	1,360	10,200,000	0.017 (1 minute)	173,400

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

According to the American Pharmacists Association, of the approximately 56,000 community-based pharmacies in the United States, about 7,500 pharmacies specialize in compounding services.[1] We estimate that veterinarians will write approximately 11,339,400 prescriptions for compounded animal drugs annually, as reported in table 2. Based on our experience with the regulation of compounded animal drugs, we estimate that from 75 to 90 percent of these prescriptions will require the compounder to document the rationale described in section III.A.6 of the draft guidance. Using the upper-bound estimate of 90 percent, approximately 10,205,460 prescriptions (0.90 × 11,339,400 prescriptions) will require compounders to keep the additional record. Dividing these prescriptions equally among the approximately 7,500 compounding pharmacies, we estimate that the 7,500 compounding pharmacies will, on average, each produce approximately 1,360 compounded animal drugs annually for a total of 10,200,000 filled prescriptions. We estimate that it will take approximately 1 minute (0.017 hours) to document the rationale described in section III.A.6 of the draft guidance for each compounded animal drug for a total of 173,400 hours, as reported in table 1.

Section III.C.3 of the draft guidance provides that if the compounded drug is compounded for use as an antidote for food-producing animals, the veterinarian establishes and documents a scientifically based withdrawal time that ensures residues of the antidote and the underlying toxin are not present in the animal at the time of slaughter or the veterinarian ensures the animal does not enter the food supply. We tentatively

[1] American Pharmacists Association, ''Frequently Asked Questions About Pharmaceutical Compounding,'' n.d., *https://www.pharmacist.com/frequently-asked-questions-about-pharmaceutical-compounding* (accessed March 19, 2019).

conclude that it is usual and customary for veterinarians to establish and document a scientifically based withdrawal time as a matter of maintaining an adequate medical record in routine practice; therefore, no burden has been estimated for the time it would take for a veterinarian to make this record.

Under 5 CFR 1320.3(b)(2), the time, effort, and financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities. As discussed, we tentatively conclude that it is usual and customary for veterinarians to keep, in the normal course of their activities, the type of records described in the draft guidance in sections III.A.4, III.A.5, and III.C.3; therefore, no burden has been estimated for such veterinary recordkeeping.

Third-Party Disclosure: Section III.A.3 of the draft guidance provides that the compounded drug should be dispensed, after receipt of a prescription for an identified patient from the veterinarian acting within a valid veterinarian-client-patient relationship (VCPR), directly to the prescribing veterinarian or to the patient's owner or caretaker. We tentatively conclude that it is usual and customary for veterinarians to write prescriptions for an identified patient in the normal course of their activities; therefore, no burden has been estimated for the time it would take for a veterinarian to write a prescription.

However, the draft guidance sets forth additional third-party disclosure provisions. Section III.A.4 of the draft guidance provides: If the compounded drug is a copy of a marketed FDA-approved, conditionally approved, or indexed animal drug or an FDA-approved human drug, there is a difference between the compounded drug and the FDA-approved, conditionally approved, or indexed animal drug or an FDA-approved human drug that will produce a clinical difference in the identified patient, ''and the medical rationale is documented in the prescription. . . .'' For example, the veterinarian could state that, ''The patient requires a 1.0% solution and the FDA-approved solution is 0.1%.'' In addition, Section III.A.5 of the draft guidance sets forth the following additional third-party disclosure provisions: (1) If the compounded drug contains the same active moiety as a marketed FDA-approved, conditionally approved, or indexed animal drug or an FDA-approved human drug but as a different salt, ester, or other noncovalent derivative; (2) if there is a difference between the compounded drug and the marketed FDA-approved, conditionally approved, or indexed animal drug or FDA-approved human drug that will produce a clinical difference in the identified patient; and (3) ''the medical rationale is documented in the prescription. . . .'' We tentatively conclude that it is not usual and customary for veterinarians to include either one of these medical rationales in a prescription in the normal course of their activities; therefore, we estimate the time it would take for a veterinarian to add a medical rationale to a prescription, as follows.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Statements on prescription (sections III.A.4 and 5 of the draft guidance).	113,394	100	11,339,400	0.017 (1 minute)	192,770

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

We base our estimate of the number of respondent veterinarians on the American Veterinary Medical Association's Market Research Statistics for 2018.[2] We estimate that approximately 113,394 veterinarians will, on average, each produce approximately 100 prescriptions for compounded animal drugs annually for a total of 11,339,400 prescriptions. We also estimate that it will take approximately 1 minute (0.017 hours) to include the statement discussed in section III.A.5 of the draft guidance on each prescription for a total of 192,769.8 hours, rounded to 192,770 hours third-party disclosure burden, as reported in table 2.

In addition, the draft guidance provides for the labeling of animal drugs compounded from bulk drug substances. The draft guidance indicates in sections III.A.8, III.B.6, and III.C.5 that pharmacists and veterinarians should label the compounded drug with a variety of information including: (1) The name of the drug; (2) the strength of the drug; (3) identifying information about the patient including the species of the patient, the name of the patient, (4) identifier for the individual animal (*e.g.,* horse in stall X), or identification of a group of animals (*e.g.,* dogs in shelter kennel X); (5) indications for which the drug will be used (for certain animal drugs without a patient specific prescription (*i.e.,* office stock) and compounded drugs for use as antidotes for food-producing animals); (6) the name, address, and contact information for the compounding pharmacy or compounding veterinarian and name of prescribing veterinarian (for office stock, the name, address, and contact information for the veterinarian ordering the office stock); (7) the beyond use date; and (8) for compounded drugs for use as antidotes for food-producing animals, the veterinarian-determined withdrawal time. We tentatively conclude that it is usual and customary for pharmacists and veterinarians to include such information on the labels of compounded animal drugs in the normal course of their activities; therefore, no burden has been estimated for the time it would take for such labeling.

Finally, sections III.A.8 and III.C.5 of the draft guidance indicates that pharmacists and veterinarians should include on the label of any compounded animal drug from bulk drug substances these three statements:

- ''Report adverse events to FDA using online Form FDA 1932a'';
- ''This is a compounded drug''; and
- ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

Similarly, section III.B.6 of the draft guidance indicates that pharmacists and veterinarians should include on the label of any animal drug compounded from bulk drug substances as office stock these four statements:

[2] The AVMA's Market Research Statistics—U.S. Veterinarians—2018 can be found at this URL: *https://www.avma.org/KB/Resources/Statistics/Pages/Market-research-statistics-US-veterinarians.aspx.*

• ''Report adverse events to FDA using online Form FDA 1932a'';

• ''This is a compounded drug'';

• ''Not for use in food-producing animals''; and

• ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.''

We tentatively conclude that these label statements are public disclosures of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)) and are therefore not subject to review by OMB under the PRA. Thus, no burden has been estimated for the time it would take for such labeling.

The draft guidance also refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information regarding voluntary reporting of adverse drug experiences or product/manufacturing defects on Form FDA 1932a, ''Veterinary Adverse Drug Reaction, Lack of Effectiveness or Product Defect Report,'' have been approved under OMB control number 0910–0284.

Before the proposed information collection provisions contained in this draft guidance become effective, we will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the proposed information collection provisions. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

V. Electronic Access

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

Dated: November 14, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–25139 Filed 11–19–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–4187]

A New Era of Smarter Food Safety; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of public meeting and request for comments that appeared in the **Federal Register** of September 18, 2019. The notice announced a public meeting entitled ''A New Era of Smarter Food Safety'' that was held on October 21, 2019. In the notice of public meeting and request for comments, FDA requested comments on a modern approach the Agency is taking to strengthen its protection of the food supply to help shape an FDA blueprint for a new era of smarter food safety. The Agency is taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice published September 18, 2019 (84 FR 49111). Submit either electronic or written comments by December 5, 2019.

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 December 5, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 5, 2019. 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–2019–N–4187 for ''A New Era of Smarter Food Safety.'' 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