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# **Waivers, Exceptions, and Exemptions From the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry**

**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Drug Evaluation and Research (CDER)  
Center for Biologics Evaluation and Research (CBER)**

**August 2023  
Administrative/Procedural**

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*Contains Nonbinding Recommendations*

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# **Waivers, Exceptions, and Exemptions From the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act Guidance for Industry<sup>1</sup>**

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. 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. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

## **I. INTRODUCTION**

This guidance describes the process an authorized<sup>2</sup> trading partner<sup>3</sup> or other stakeholder should use to request a waiver, exception, or exemption from the requirements of section 582 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360eee-1), as amended by the Drug Supply Chain Security Act (DSCSA) (Title II of Public Law 113-54). This guidance also describes the factors the Food and Drug Administration (FDA) intends to consider when evaluating such requests from an authorized trading partner or other stakeholder, and when determining FDA-initiated exceptions and exemptions. Additionally, this guidance describes the process the FDA intends to follow once every two years to review and make determinations on the appropriateness of renewing a previously approved waiver, exception, or exemption, where applicable. This guidance finalizes the draft guidance for industry *Waivers, Exceptions, and Exemptions from the Requirements of Section 582 of the Federal Food, Drug, and Cosmetic Act*, issued in May 2018 as required by section 582(a)(3) of the FD&C Act. The revisions described in this document update the policy articulated in the May 2018 draft guidance.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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<sup>1</sup> This guidance has been prepared by the Office of Compliance in the Center for Drug Evaluation and Research (CDER) in cooperation with the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration.

<sup>2</sup> *Authorized* is defined in section 581(2) of the FD&C Act.

<sup>3</sup> *Trading partner* is defined in section 581(23) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B) of the FD&C Act, the provisions of sections 582(b)-(e) of the FD&C Act do not impose requirements on those entities.

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### II. BACKGROUND

The DSCSA outlines critical steps to enhance drug distribution security. These steps will ultimately allow tracing of certain human finished prescription drugs in an electronic, interoperable manner as they are distributed within the United States (U.S.). Section 582 of the FD&C Act, as amended by the DSCSA, applies to manufacturers, repackagers, wholesale distributors and dispensers (collectively referred to as “trading partners”) who engage in transactions of product,<sup>4</sup> and outlines requirements related to product tracing, verification, product identification, and authorized trading partners.

Section 582(a)(3)(A) of the FD&C Act requires the FDA to issue a guidance that:

(i) establish[es] a process by which an authorized manufacturer, repackager, wholesale distributor, or dispenser may request a waiver from any of the requirements set forth in [section 582 of the FD&C Act], which the Secretary may grant if the Secretary determines that such requirements would result in an undue economic hardship or for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act;<sup>5</sup>

(ii) establish[es] a process by which the Secretary determines exceptions, and a process through which a manufacturer or repackager may request such an exception, to the requirements relating to product identifiers if a product is packaged in a container too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with [section 582 of the FD&C Act]; and

(iii) establish[es] a process by which the Secretary may determine other products or transactions that shall be exempt from the requirements of [section 582 of the FD&C Act].

Additionally, section 582(a)(3)(B) of the FD&C Act requires the FDA to issue guidance that includes a process on how the FDA intends to review and renew granted waivers, exceptions, and exemptions.

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<sup>4</sup> *Product* is defined in section 581(13) of the FD&C Act.

<sup>5</sup> The emergency medical reason waiver described in section 582(a)(3)(A)(i) of the FD&C Act is distinct from the emergency medical reason statutory exemption in section 581(24)(B)(iii) of the FD&C Act and exclusion in section 503(e)(4)(C) of the FD&C Act. Specifically, the emergency medical reason waiver in section 582(a)(3)(i) of the FD&C Act can extend to section 582 requirements that are not within the purview of the statutory exemption described in section 581(24)(B)(iii) of the FD&C Act and exclusion in section 503(e)(4)(C) of the FD&C Act for the definitions of *transaction* and *wholesale distribution*, respectively. For purposes of the statutory exemption in section 581(24)(B)(iii) of the FD&C Act and exclusion in section 503(e)(4)(C) of the FD&C Act, a public health emergency declared under section 319 of the Public Health Service Act is automatically considered an “emergency medical reason” under the DSCSA. Upon declaration of a public health emergency, product distribution for such emergency medical reasons is exempted from the definition of a *transaction* and excluded from the definition of *wholesale distribution*” under the DSCSA. As a result, the DSCSA requirements related to product tracing and product identification triggered by a “transaction” and the DSCSA requirements related to wholesale distribution do not apply to trading partner activities that address the public health emergency declaration for the duration of the public health emergency. All other DSCSA requirements apply.

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### **III. PROCESS FOR SUBMITTING WAIVER, EXCEPTION, OR EXEMPTION REQUESTS TO FDA**

This section provides essential information that describes the process to submit a waiver, exception, or exemption request to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drug Evaluation and Research (CDER). FDA recommends that all correspondence between FDA and a trading partner or other stakeholder, including submission of an initial request and subsequent communication associated with an initial or granted request, be exchanged electronically in a manner that is consistent with the procedures articulated in section III.C. of this document.

#### **A. Entities that May Submit a Request**

Only an authorized manufacturer, repackager, wholesale distributor, or dispenser<sup>6</sup> may request a waiver under section 582(a)(3)(A)(i) of the FD&C Act, and only a manufacturer or repackager may request an exception under section 582(a)(3)(A)(ii) of the FD&C Act.<sup>7</sup> Any interested stakeholder may request an exemption under section 582(a)(3)(A)(iii) of the FD&C Act.

#### **B. Information to Include in a Request**

##### *1. Request-specific Information*

Each request should include the following information:

- Name, telephone number, and email address of an individual who FDA can contact about matters relating to the proposed waiver, exception, or exemption<sup>8</sup>
- Name and address of the trading partner(s) that the proposed waiver, exception, or exemption would cover
- Description of the activities and/or products (including the product name and National Drug Code number) for which the proposed waiver, exception, or exemption is being sought
- Identification of the specific statutory provision(s) of section 582 of the FD&C Act to which the proposed waiver, exception, or exemption would apply
- Description of the measures or controls that will be implemented to ensure the

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<sup>6</sup> *Manufacturer, wholesale distributor, dispenser, and repackager* are defined in sections 581(10), (29), (3), and (16) of the FD&C Act, respectively.

<sup>7</sup> An authorized representative of a trading partner, such as legal counsel and consultants, may submit a waiver or exception request on behalf of the trading partner.

<sup>8</sup> It is the responsibility of the requesting trading partner or other stakeholder to inform FDA of changes in contact information.

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safety and security of the drug supply chain while operating under a waiver, exception, or exemption

- Requested effective period (e.g., start and end date) of the proposed waiver, exception, or exemption
- Unique or special circumstances of a product and/or transaction
- Detailed statement describing the reason(s) justifying the proposed waiver, exception, or exemption request as well as pertinent supporting documentation, as applicable, to support the request

### *2. Attestation*

In addition, please affirm the following statement in your request:

*I affirm that the information in this statement is correct, and I understand that under 18 U.S.C. 1001 it is illegal to make a materially false, fictitious, or fraudulent statement or representation in this matter within FDA's jurisdiction.*

## **C. How to Submit a Request**

FDA recommends that an authorized trading partner or other stakeholder seeking a waiver, exception, or exemption from requirements of section 582 of the FD&C Act submit an electronic request to FDA. FDA strongly encourages electronic submission to facilitate efficiency and timeliness of submission and review. A table is provided in the Appendix to summarize where requests and subsequent communication associated with an initial or granted request should be submitted. Following the submission of a request, FDA intends to provide the trading partner or other stakeholder an acknowledgement confirming receipt of the request.

### *1. Submissions to FDA for CBER-regulated Products*

A request for a waiver, exception, or exemption for products that CBER reviews should be submitted as product correspondence to the biologics license application (BLA), new drug application (NDA), or abbreviated new drug application (ANDA) in the electronic common technical document (eCTD) format.<sup>9</sup>

For submissions related exclusively to CBER-regulated products but not associated with a specific application(s), a request should be sent to [DSCSA-CBER-WEER@fda.hhs.gov](mailto:DSCSA-CBER-WEER@fda.hhs.gov).

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<sup>9</sup> See the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* (February 2020). We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

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### ***2. Submissions to FDA for CDER-regulated Products***

A request for a waiver, exception, or exemption for products that CDER reviews should be submitted through FDA's CDER NextGen Portal. All new users to the CDER NextGen Portal who intend to submit a request should register for an account prior to creating and submitting a request for a waiver, exception, or exemption to FDA. In addition, subsequent communications made between CDER and a trading partner or stakeholder associated with an initial or granted request for a waiver, exception, or exemption, should be made utilizing FDA's CDER NextGen Portal.

Access to the CDER NextGen Portal as well as information and tutorials on how to access the application are located on FDA's CDER NextGen Portal web page, which can be found at <https://edm.fda.gov>.<sup>10</sup>

#### **D. Notifying FDA of Material Changes**

The recipient(s) of a waiver, exception, or exemption should notify the FDA Center that originally issued the waiver, exception, or exemption whenever there is a material change in the circumstances that formed the basis for granting the initial request for regulatory relief. Furthermore, recipient(s) should notify FDA as soon as possible and FDA recommends no later than 12 business days following the change, regardless of the duration of the waiver, exception, or exemption.

The following example is for illustrative purposes and should not be construed as exhaustive of all circumstances for when a material change occurs. The example is intended to help trading partners and stakeholders understand when they should notify FDA of a material change.

*A manufacturer receives an exception from FDA for a product packaged in a container that is too small to accommodate a label with space to bear a product identifier. The exception has an effective period of three years. One year after receiving the exception, the manufacturer begins packaging the product in a larger container that can accommodate a label with a product identifier. In this scenario, the manufacturer should notify FDA of this material change when it begins production of product utilizing the larger container as opposed to waiting until FDA's biennial review of the valid exception.*

If the recipient of a waiver, exception, or exemption is unsure about whether a material change has occurred, the recipient should contact FDA as soon as possible using the applicable steps in section III.C. of this guidance.

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<sup>10</sup> Waiver, exception, and exemption requests that are not related to specific products or where the lead center is uncertain or unknown should be submitted through FDA's CDER NextGen Portal, which can be found at <https://edm.fda.gov>.



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### **IV. PROCESS FOR REVIEWING AND DETERMINING WAIVER, EXCEPTION, OR EXEMPTION REQUESTS**

#### **A. Review of Requests**

FDA intends to evaluate each request on a case-by-case basis to ensure that it contains sufficient information to permit a substantive review. FDA may also use its discretion to contact a requesting trading partner or other stakeholder to clarify an aspect of the request (e.g., the products or transactions that the request covers) or to request additional information related to the subject of the request. If FDA determines that a request lacks sufficient information to permit a substantive review or a requesting trading partner or other stakeholder fails to provide requested clarifying information, the Agency may deny the request.

During the review, FDA may consult with relevant subject matter experts within the Agency as appropriate and assess, as applicable, whether:

- A waiver of the FD&C Act section 582 requirement(s) identified in the request is (1) warranted because complying with the requirement(s) would result in undue economic hardship or (2) appropriate for emergency medical reasons;
- An exception to the FD&C Act section 582 requirements relating to product identifiers is warranted because the product identified in the request is packaged in a container that is too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with these requirements; or
- Exempting the product(s) and/or transaction(s) identified in the request from the FD&C Act section 582 requirement(s) identified in the request is appropriate to maintain public health or is otherwise appropriate.

FDA intends to also consider the potential risks that a proposed waiver, exception, or exemption may pose to the security of the drug supply chain. Additionally, if the submission seeks a waiver, exception, or exemption that could affect a broad segment(s) of industry and/or multiple trading partners, FDA may deny or defer the request if it determines that an FDA-initiated exception, exemption, or other regulatory action would be more appropriate.

#### **B. Determining Requests and Notifying Affected Entities**

Once FDA has received and reviewed all relevant information and documentation to support a waiver, exception, or exemption request, FDA intends to notify the requesting trading partner or other stakeholder of the Agency's determination to grant, deny, or take other appropriate action on the original request. The Agency intends to assess requests received in a timely manner; however, the timeframe to complete a review and notify the requesting trading partner or other stakeholder of its determination may vary depending on the nature of the request or the volume of requests under assessment by the Agency at that time. In its notification, FDA intends to include an explanation of the basis for the determination and, if granted, the effective and termination date of the waiver, exception, or exemption. To minimize the potential risks to the drug supply

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chain that a waiver, exception, or exemption may incur, FDA may limit the duration of a waiver, exception, or exemption based upon the nature of the circumstances surrounding a request. However, FDA may grant a request for an undetermined period to address situations that involve extraordinary circumstances.

Additionally, to help ensure that trading partners in the supply chain are aware of a granted waiver, exception, or exemption, the recipient should notify its trading partners of such a waiver, exception, or exemption.<sup>11</sup> The Agency may, in its discretion, post information regarding a determination to its website if it concludes that doing so is in the best interest of, or is necessary to protect, public health. Such information would be posted in a manner that is consistent with the laws and regulations governing the disclosure of confidential commercial information.

FDA recognizes that a granted waiver, exception, or exemption may affect DSCSA requirements of downstream trading partners transacting product with the recipient of a waiver, exception, or exemption. In FDA's response to the recipient of a waiver, exception, or exemption, FDA intends to provide corresponding relief for DSCSA requirements of downstream trading partners. Additionally, FDA anticipates that product for which a waiver, exception, or exemption has been granted may continue to be the subject of transactions beyond the granted effective period. For product that may remain in the supply chain beyond the effective period of a granted waiver, exception, or exemption, the Agency intends to also address those unique scenarios in its response to the recipient.

### **C. Reconsideration of a Granted Waiver, Exception, or Exemption**

If the recipient wants FDA to reconsider the scope of a waiver, exception, or exemption that has been granted, the recipient may submit a request for reconsideration and should include information adequate to explain the nature of the issue when submitting the request. Additionally, new information should be provided to FDA to justify a change in FDA's prior conclusions concerning the scope of the waiver, exception, or exemption using the applicable steps in section III.C. of this guidance. Following the submission of a request to reconsider the scope of a waiver, exception, or exemption that has been granted, FDA intends to issue an acknowledgement to the trading partner or other stakeholder confirming receipt of the request. After FDA reviews the information submitted, the Agency intends to issue a response to the requesting trading partner or other stakeholder, setting forth the basis of its decision.

### **D. Reconsideration of a Denied Request**

If the recipient wants FDA to reconsider a denied request for a waiver, exception, or exemption, a recipient may submit a request for the Agency to reconsider and re-evaluate the denied request. In the request, the recipient should provide additional information, such as updated

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<sup>11</sup> In addition to notifying its trading partners of a granted waiver, exception, or exemption, FDA recommends that the recipient maintain readily accessible resources for its trading partners that provide: (1) notification to trading partner(s) about the FD&C Act section 582 requirement(s) that is waived, excepted, or exempted; and (2) a phone number and/or email address of the recipient that trading partner(s) may contact to obtain timely confirmation of the product(s) or transaction(s) subject to the waiver, exception, or exemption. The resource should be maintained until the latest date of expiry of products covered under the waiver, exception, or exemption.

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documentation or analysis not previously provided to support the waiver, exemption, or exemption, using the applicable steps in section III.C. of this guidance. FDA recommends this information to be provided as soon as possible and preferably no later than 12 business days after the date of the denial. Depending on the scope of information received in the request for reconsideration, and when the request is received, FDA may consider such requests in the context of a new waiver, exception, or exemption request. In this case, FDA intends to inform the requestor, and the trading partner or stakeholder should submit a new request with supporting information, as needed, using the steps applicable in section III.C. of this guidance.

Following the submission of a request to reconsider and re-evaluate a denied request, FDA intends to issue an acknowledgement to the trading partner or other stakeholder confirming receipt of the request. After FDA reviews the information submitted, the Agency intends to issue a response to the requesting trading partner or other stakeholder, setting forth the basis of its decision to affirm the denial decision or grant the requested waiver, exception, or exemption.

## **V. PROCESS FOR FDA-INITIATED EXCEPTIONS AND EXEMPTIONS**

Under sections 582(a)(3)(A)(ii) and (iii) of the FD&C Act, FDA can establish exceptions or exemptions from the requirements of section 582 of the FD&C Act on its own initiative.<sup>12</sup> FDA intends to use this authority when necessary to address an issue that affects a broad segment(s) of industry and/or multiple trading partners, impacts many drug distribution activities, or involves numerous products.

Consistent with the approach described in section IV. of this guidance, FDA intends to only establish exceptions under section 582(a)(3)(A)(ii) of the FD&C Act on its own initiative when the Agency determines that the excepted product(s) is packaged in a container that is too small or otherwise unable to accommodate a label with sufficient space to bear the information required for compliance with the section 582 requirements relating to product identifiers. Similarly, FDA intends to only establish exemptions under section 582(a)(3)(A)(iii) of the FD&C Act on its own initiative when the Agency determines that the exemption is appropriate to maintain public health or is otherwise appropriate. As with exceptions and exemptions that are granted pursuant to a request from an authorized trading partner or other stakeholder, FDA intends to consider how an exception or exemption may affect the security of the drug supply chain prior to establishing the exception or exemption on its own initiative.

If FDA establishes an exception or exemption to address a particular issue, the Agency intends to communicate the information in writing using a method that is appropriate for the circumstances (e.g., issuing a letter to the affected trading partners or posting on the Agency's website if an exception or exemption applies to a broad segment of industry). An exception or exemption that FDA establishes may be limited in duration or valid until further notice from the Agency.

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<sup>12</sup> See sections 582(a)(3)(A)(ii) and (iii) of the FD&C Act.

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### **VI. REVIEW AND RENEWAL OF WAIVER, EXCEPTION, AND EXEMPTION REQUESTS**

#### **A. Biennial FDA Review and Renewal of Waivers, Exceptions, and Exemptions**

The FDA has discretion regarding whether to approve a waiver, exception, or exemption for the duration specified in the request or for an alternative duration. For those requests that are approved, once every two years, FDA intends to review waivers, exceptions, and exemptions with an expiration date of an indeterminate period or longer than two years after the effective date, and renew such waivers, exceptions, and exemptions, as applicable. During this review, the Agency intends to assess, among other things, whether a material change in circumstances has occurred, thereby making the waiver, exception, or exemption unwarranted. To assess whether a material change in circumstances has occurred, the Agency may request supporting documentation from the recipient of an approved waiver, exception, or exemption to substantiate the continued need for such a request. For example, an authorized trading partner that received an “undue economic hardship” waiver may be asked to submit updated financial information demonstrating that the circumstances supporting the original waiver decision still exist.

#### **B. Authorized Trading Partner Renewal Requests of Expiring Waivers, Exceptions, and Exemptions**

An authorized trading partner or other stakeholder may submit a renewal request for any waiver, exception, or exemption it received that is of limited duration. A renewal request should be submitted to the FDA Center that originally issued the waiver, exception, or exemption as soon as the authorized trading partner or other stakeholder determines that a renewal is necessary. The request should include a detailed statement justifying the continuance of the waiver, exception, or exemption, and the desired length of the extension. In addition, the request should contain the affirmation set forth in section III.B. of this guidance.

FDA intends to review and respond to renewal requests in the same manner that it reviews and responds to initial requests for waivers, exceptions, and exemptions.<sup>13</sup> FDA does not intend to accept renewal requests for an FDA-initiated exception or exemption. If an authorized trading partner or other stakeholder believes that renewing an expiring FDA-initiated exception or exemption after the expiration date is necessary, that trading partner or other stakeholder should submit a request for an exception or exemption.

#### **C. Terminating Previously Granted Requests and Notifying Affected Entities**

In the event FDA determines that a granted waiver, exception, or exemption is no longer appropriate following a biennial review, FDA intends to terminate the waiver, exception, or exemption prior to the expiration date. Similarly, if FDA learns – outside of the biennial review process – of circumstances that render a previously granted waiver, exception, or exemption no longer appropriate, FDA may terminate the waiver, exception, or exemption prior to the expiration date. The Agency intends to notify the requesting trading partner or other stakeholder of a previously granted waiver, exception, or exemption of its determination to terminate the

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<sup>13</sup> See sections IV.A. and IV.B. of this guidance.

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waiver, exception, or exemption. Additionally, FDA recommends that the recipient of a waiver, exception, or exemption notify its trading partners if a previously granted waiver, exception, or exemption has been terminated.

For FDA-initiated exceptions and exemptions, the Agency intends to announce the termination using a written method appropriate for the circumstances, including posting information regarding a termination to its website if it concludes that doing so is in the best interest of or is necessary to protect public health. Such information would be posted in a manner that is consistent with the laws and regulations governing the disclosure of confidential commercial information.

The Agency intends to issue these written termination notices and announcements within a reasonable amount of time before the stated termination date.

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**APPENDIX**

**Where to Submit Waiver, Exception, and Exemption Requests and Subsequent Communications**

<b>Requests related exclusively to CBER-regulated products that are associated with a BLA, NDA, or ANDA</b>	Send in eCTD format through FDA's Electronic Submissions Gateway as product correspondence to the application
<b>Requests related exclusively to CBER-regulated products that are <i>not</i> associated with a specific application(s)</b>	Send email to: <a href="mailto:DSCSA-CBER-WEER@fda.hhs.gov">DSCSA-CBER-WEER@fda.hhs.gov</a>
<b>All other requests, including those for CDER-regulated products, those that are not related to specific products, or when the lead center is uncertain or unknown</b>	Submit through FDA's CDER NextGen Portal web page at: <a href="https://edm.fda.gov">https://edm.fda.gov</a>

As explained above, FDA strongly encourages electronic submissions to facilitate efficiency and timeliness of submission and review. However, paper submissions may be submitted to the addresses below if needed:

*Submissions to FDA for CBER-regulated products:*

Food and Drug Administration  
Center for Biologics Evaluation and Research  
Document Control Center  
10903 New Hampshire Ave.  
Bldg. 71, Rm. G112  
Silver Spring, MD 20993-0002

*Submissions to FDA for CDER-regulated products, those that are not related to specific products, or when the lead center is uncertain or unknown:*

Office of Drug Security, Integrity, and Response  
Center for Drug Evaluation and Research  
Food and Drug Administration  
10903 New Hampshire Ave.  
Bldg. 51, Rm. 4203  
Silver Spring, MD 20993-0002  
Attn: DSCSA WEER Team