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CENTER FOR DRUG EVALUATION AND RESEARCH
**OUTSOURCING
FACILITY
INFORMATION**

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I. INTRODUCTION

In the Drug Quality and Security Act of 2013, Congress created a new category of compounders known as outsourcing facilities. In contrast to “traditional” compounders, outsourcing facilities can, subject to satisfying relevant legal requirements, compound and distribute drugs without receiving prescriptions for individually identified patients, and without limitation on the quantity of drugs that they ship interstate. Drugs compounded by outsourcing facilities are subject to current good manufacturing practice (CGMP) requirements, FDA inspections on a risk-based schedule, and other important conditions that provide greater assurances of the quality of their compounded drugs.

The following information is intended to assist outsourcing facilities in locating provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA policy and procedures that are relevant to their operations, and to assist compounders in deciding whether to register with FDA as outsourcing facilities.

A. Statutory Framework

Section 503B(d)(4)(A) of the FD&C Act defines an outsourcing facility as a facility at one geographic location or address that:

- Is engaged in the compounding of sterile drugs;
- Has elected to register as an outsourcing facility; and
- Complies with all of the requirements of section 503B.

An outsourcing facility is not required to be a licensed pharmacy, and it may or may not receive prescriptions for identified individual patients. Sections 503B(d)(4)(B) and (C) of the FD&C Act.

A human drug product compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility can qualify for exemptions from requirements under three sections of the FD&C Act:

- Labeling with adequate directions for use (section 502(f)(1));
- New drug approval requirements (section 505); and
- Drug supply chain security requirements (section 582).

Drugs compounded by outsourcing facilities remain subject to CGMP requirements established under section 501(a)(2)(B) of the FD&C Act, and other applicable requirements in the Act.

B. Profile of Outsourcing Facilities

Outsourcing facilities vary in terms of size and drug products produced. Some were formerly conventional manufacturing facilities and engage in large-scale production and distribution of compounded drugs. Others were or are state-licensed pharmacies that compound small batches of drug products, often pursuant to prescriptions for identified individual patients. Many compound both sterile and non-sterile drugs for both humans and animals. In addition, some outsourcing facilities, in addition to compounding sterile drugs for human use, engage in conventional manufacturing of FDA-approved drugs; mixing, diluting, and repackaging of biological products; and repackaging drugs.

Of the 59 outsourcing facilities that FDA has inspected as of August 2017:

- **25** engage in both sterile and non-sterile compounding
- **24** engage in both patient-specific and non-patient specific compounding
- **22** compound a portion of their drugs in small batches (10 units or fewer)
- **45** compound drugs from bulk drug substances
- Outsourcing facilities are located in **25** states
- **51** ship compounded drugs in interstate commerce

In addition, in a six-month period, outsourcing facilities that submitted drug product reports to FDA compounded 12,305,873 units of drugs.

II. OUTSOURCING FACILITY OPERATIONS

To meet the definition of an outsourcing facility, the facility must be engaged in the compounding of sterile human drugs (section 503B(d)(4)(A)(i)). Entities that do not compound sterile human drugs should not register as outsourcing facilities.

In addition to compounding human sterile drugs, an outsourcing facility may also compound non-sterile drugs. Drugs in either category that are compounded in accordance with the conditions of section 503B of the Act will qualify for the exemptions.

FDA has issued draft or final guidance regarding the conduct of other activities within an outsourcing facility:

- Repackage drugs as described in FDA's [guidance](#), *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities*.
- Mix, dilute, or repackage biological products as described in FDA's [guidance](#), *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application*.
- Compound animal drugs. FDA has issued a draft [guidance](#), *Compounding Animal Drugs from Bulk Drug Substances*.
- Engage in conventional manufacturing of approved drug products. See FDA's [draft guidance](#), *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

For more information, see the [guidance](#), *For Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*.

III. IMPLICATIONS OF BECOMING AN OUTSOURCING FACILITY

When deciding whether to register as an outsourcing facility, compounders should carefully consider the implications, including responsibilities of outsourcing facilities under the FD&C Act.

A. Advantages to Compounders of 503B Registration

FDA understands that many compounders have elected to register as outsourcing facilities for two main reasons:

- i. Outsourcing facilities can distribute compounded drugs for “office use” without receiving prescriptions for identified individual patients.

Compounders that have not registered as outsourcing facilities, who seek to operate under section 503A of the FD&C Act, can only distribute compounded drugs based on the receipt of valid prescriptions for identified individual patients. Section 503A(a). In contrast, section 503B states that outsourcing facilities “may or may not receive prescriptions for identified individual patients.” Section 503B(d)(4)(C). In other words, only outsourcing facilities may distribute compounded drugs to healthcare facilities and practitioners without first receiving a patient-specific prescription.

- ii. Purchasers often seek compounded drugs with a greater assurance of quality.

Because the FD&C Act subjects outsourcing facilities to CGMP requirements and Federal oversight, including inspections on a risk-based schedule, specific adverse event reporting requirements, and other conditions, healthcare practitioners who purchase compounded drugs for their patients often source such drugs from outsourcing facilities.

B. Requirements under the FD&C Act

Outsourcing facilities must comply with all applicable requirements of the FD&C Act, including, but not limited to, CGMP requirements and the conditions of section 503B.

- i. Compliance with applicable quality standards

Outsourcing facilities are required to comply with CGMP requirements under section 501(a)(2)(B) of the FD&C Act. Under section 501(a)(2)(B), a drug is deemed to be adulterated if it is not produced in accordance with CGMP requirements. FDA’s regulations regarding CGMP requirements for the preparation of drug products have been established in 21 CFR parts 210 and 211. FDA intends to promulgate more specific CGMP regulations for outsourcing facilities. FDA has issued a draft [guidance](#), *Current Good Manufacturing Practice—Interim Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act*, that, once final, will describe FDA’s expectations regarding outsourcing facilities and the CGMP requirements in 21 CFR parts 210 and 211 until more specific CGMP regulations for outsourcing facilities are promulgated.

The draft guidance reflects FDA's intent to recognize the differences between compounding outsourcing facilities and conventional drug manufacturers, and to tailor CGMP requirements to the nature of the specific compounding operations conducted by outsourcing facilities while maintaining the minimum standards necessary to protect patients from the risks of contaminated or otherwise substandard compounded drug products.

Outsourcing facilities are also subject to other adulteration provisions of the FD&C Act, including the prohibition on preparing, packing, or holding drugs under insanitary conditions whereby they may become adulterated with filth or rendered injurious to health. Section 501(a)(2)(A). Outsourcing facilities also may not produce drugs that are contaminated with filth or super- or sub-potent. Sections 501(a)(1), 501(b), 501(c), 502(a), and 502(j).

ii. Compliance with the conditions of section 503B of the FD&C Act

To meet the statutory definition of an outsourcing facility, and for the compounder's drugs to qualify for the exemptions in section 503B, it must produce all of its compounded drugs in accordance with all of the conditions of section 503B. Section 503B(d)(4)(A)(iii), 503B(a)(11). Examples of conditions in section 503B include, but are not limited to:

- Limitations on bulk drug substances that can be used in compounding (section 503B(a)(2))
- Prohibition on compounding drugs that appear on the list of drugs at 21 CFR 216.24 that have been withdrawn or removed from the market because the drugs or components of the drugs have been found to be unsafe or not effective (section 503B(a)(4))
- Prohibition on compounding drugs that are essentially a copy of one or more approved drugs (section 503B(a)(5))
- Labeling requirements (section 503B(a)(10))
- Drug product reporting requirements (sections 503B(a)(1) and 503B(b)(2))
- Adverse event reporting requirements (sections 503B(a)(1) and 503B(b)(5))

iii. Payment of fees required by sections 503B and 744K of the FD&C Act

Upon initial registration and each year that the entity renews its registration, sections 503B and 744K of the FD&C Act require FDA to assess each outsourcing facility an establishment registration fee of \$15,000, or \$5,000 for small businesses, adjusted each year for inflation. In addition, FDA must assess a fee of \$15,000, adjusted for inflation, for each reinspection that it conducts. A reinspection is an inspection conducted after an inspection in which FDA identified noncompliance materially related to an applicable requirement of this Act, specifically to determine whether compliance has been achieved to the FDA's satisfaction.

See the [guidance](#), *Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act* for more information about relevant fees, including how to apply for the small business reduction.

IV. RESOURCES AVAILABLE TO OUTSOURCING FACILITIES

A. Meetings with FDA and Pre-Operational Reviews

In general, FDA is unable to grant most requests for meetings from stakeholders regarding implementation of the compounding provisions of the FD&C Act because of limited resources. However, to facilitate compliance in this new industry, FDA entertains, as resources permit, requests from outsourcing facilities and compounders considering registering as outsourcing facilities to meet with the agency regarding questions about compliance with CGMP requirements and the conditions of section 503B.

In addition, as resources permit, FDA conducts, upon request, preoperational site evaluations of outsourcing facilities to assess facility design, standard operating procedures, and other conditions that are critical to producing sterile drug products before the outsourcing facility initiates production for distribution.

B. Guidance Documents and Regulations

FDA has issued or intends to issue guidance documents that can assist outsourcing facilities in complying with section 503B of the FD&C Act, as well as certain relevant regulations.

FD&C Act Citation	Text of Section 503B	Applicable FDA Draft or Final Policy Documents
Section 503B(a)	Compounding must be by or under the direct supervision of a licensed pharmacist.	FDA intends to issue a policy document on this provision in the future.
Sections 503B(a)(1), 503B(b) and 301(ccc)(3)	The outsourcing facility is in compliance with the registration and reporting requirements of section 503B(b). This includes submitting twice yearly reports regarding the drugs compounded by the outsourcing facility and submitting adverse event reports in accordance with section 503B(b)(5).	<p><u>Establishment Registration</u> See the final guidance, <i>Registration of Human Drug Compounding Under Section 503B of the FD&C Act</i>.</p> <p>This guidance describes the process for electronic submission of establishment registration information for outsourcing facilities.</p> <p><u>Drug Product Reporting</u> See the final guidance, <i>Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act</i>.</p> <p>This guidance describes who must report and what information they must provide and explains that drug compounding reports must be submitted in structured product labeling (SPL) format using FDA’s electronic submissions system.</p> <p><u>Adverse Event Reporting</u> See the final guidance, <i>Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act</i>.</p>

		Under section 503B(b)(5) of the FD&C Act, an outsourcing facility must submit adverse event reports to FDA “in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).” This guidance explains FDA’s current thinking on adverse event reporting for outsourcing facilities
Section 503B(a)(2)	<p>If the outsourcing facility compounds drugs using bulk drug substances, the substances are either used to compound drugs on FDA’s drug shortage list, or they appear on a list developed by FDA of bulk drug substances that can be used in compounding under section 503B (“bulks list”).</p> <p>In addition, the bulk drug substances are accompanied by a valid certificate of analysis and were manufactured by FDA-registered establishments.</p>	<p>See the final guidance, <i>Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act</i>.</p> <p>This guidance describes FDA’s policy for outsourcing facilities compounding from bulk drug substances that are not used to compound drugs on FDA’s drug shortage list, while the bulks list is in development.</p> <p>Interested parties can nominate bulk drug substances for use in compounding at regulations.gov, docket FDA-2015-N-3469.</p>
Section 503B(a)(3)	If any ingredients (other than bulk drug substances) are used in compounding the drug, such ingredients comply with the standards of the applicable United States Pharmacopeia or National Formulary monograph, if such monograph exists, or of another compendium or pharmacopeia recognized by the FDA for purposes of this paragraph if any.	N/A
Section 503B(a)(4)	The outsourcing facility does not compound drugs that appear on a list published by FDA of drugs that have been withdrawn or removed from the market because the drugs or components of such drugs have been found to be unsafe or not effective.	The list of drugs that have been withdrawn or removed from the market because the drugs or components of the drugs have found to be unsafe or ineffective appears at 21 CFR 216.24 .
Sections 503B(a)(5), 503B(d)(2)	The outsourcing facility does not compound drugs that are essentially a copy of one or more approved drugs.	<p>See the draft guidance, <i>Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act</i>.</p> <p>This guidance describes policies concerning the “essentially a copy” provision of section 503B, including policies concerning the definition of this term.</p>
Section 503B(a)(6)	The outsourcing facility does not compound drugs that appear on a list published by FDA of drugs or categories of drugs that present demonstrable difficulties for compounding.	<p>FDA has not yet developed this list.</p> <p>Interested parties can nominate substances for this list at www.regulations.gov, docket FDA-2017-N-2562.</p>
Section 503B(a)(7)	If the outsourcing facility compounds a drug that is the subject of a risk evaluation and mitigation strategy (REMS) approved with elements to assure safe use pursuant to section 505-1, or from a bulk drug substance that is a component of such drug, the outsourcing facility must demonstrate to FDA before beginning to compound that it will use controls comparable to the controls applicable under the REMS.	FDA intends to issue guidance explaining the process and content of submissions to the agency.

Section 503B(a)(8)	The outsourcing facility's compounded drugs will not be sold or transferred by an entity other than that outsourcing facility.	FDA intends to issue a policy document on this provision in the future.
Sections 503B(a)(9), 744J, 744K	The outsourcing facility has paid all applicable establishment and reinspection fees owed under section 744K.	See FDA's final guidance , <i>Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act</i> . This guidance describes the types and amounts of fees that outsourcing facilities must pay, the adjustments to fees required by law, how outsourcing facilities can submit payment to FDA, the consequences of outsourcing facilities' failure to pay fees, and how an outsourcing facility can qualify as a small business to obtain a reduction in fees
Section 503B(a)(10)	Outsourcing facilities must label their drugs and containers with certain information.	FDA intends to issue a policy document on this provision in the future.
Section 503B(a)(11)	All of the human drugs compounded within an outsourcing facility must be compounded only in accordance with section 503B.	See FDA's final guidance , <i>For Entities Considering Whether to Register as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act</i> . This guidance explains, among other things, that drugs compounded within an outsourcing facility cannot qualify for the exemptions in section 503A. See also, FDA's draft guidance, <i>Facility Definition under Section 503B of the Federal Food, Drug, and Cosmetic Act</i> . This guidance explains FDA's interpretation of the term "facility at one geographic location or address" in section 503B's definition of an outsourcing facility.

FDA has also issued the following guidance documents regarding drug production operations other than compounding of human drugs by outsourcing facilities.

Drug Production Activity	Applicable FDA Draft or Final Policy Documents
Repackaging drugs	See FDA's final guidance , <i>Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities</i> . FDA regards repackaging as the act of taking a finished drug product from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the drug. Repackaged drug products are not eligible for exemptions under section 503B of the FD&C Act, but are generally subject to the adulteration, misbranding, and approval provisions of the FD&C Act. Accordingly, this guidance describes, among other things, the conditions under which FDA does not intend to take action for violations of sections 505, 502(f)(1), and 582 when an outsourcing facility repackages drug products.

Mixing, diluting, or repackaging biological products	<p>See FDA’s draft guidance, <i>Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application</i>.</p> <p>Biological products are not eligible for exemptions under section 503B of the FD&C Act, and are generally not exempt from any of the provisions of the FD&C Act related to the production of drugs. This guidance, if finalized, will describe conditions under which FDA does not intend to take action when certain biological products are mixed, diluted, or repackaged by an outsourcing facility in a manner not described in their approved labeling.</p>
Compounding animal drugs from bulk drug substances	<p>See FDA’s draft guidance, <i>Compounding Animal Drugs from Bulk Drug Substances</i>.</p> <p>Animal drugs are not eligible for exemptions under section 503B of the FD&C Act and are generally subject to the adulteration, misbranding, and approval provisions of the FD&C Act. Accordingly, when finalized, this guidance will generally describe, among other things, the conditions under which FDA does not intend to take action for violations of sections 501(a)(5) and 502(f)(1) of the FD&C Act when an outsourcing facility compounds animal drugs from bulk drug substances.</p>

C. Contacting the Agency

Outsourcing facilities and compounders considering registering as outsourcing facilities can submit questions, meeting requests, and other messages to the Compounding Team in FDA’s Center for Drug Evaluation and Research at Compounding@fda.hhs.gov.

Correspondence related to inspections and regulatory actions should be sent to the contact in FDA’s Office of Regulatory Affairs listed on your Form FDA-482 or regulatory letter.

V. HOW TO REGISTER AS AN OUTSOURING FACILITY AND SUBMIT DRUG PRODUCT REPORTS

A. Establishment Registration

To register as an outsourcing facility, a compounder must use the electronic registration system ([go to CDER Direct](#)) (unless FDA grants a waiver) to provide the following information: name; place of business; unique facility identifier; point of contact email address; an indication of whether the facility intends to compound products on FDA’s drug shortage list; an indication of whether the facility compounds from bulk drug substances, and if so, whether it compounds sterile drugs from bulk drug substances.

Once FDA receives the electronic registration submission, it sends the registrant an invoice for the establishment registration fee that must be paid at the time of registration. The amount of this fee and directions for paying the fee are published in the *Federal Register*, which appears on FDA.gov under [Regulatory Policy Information](#).

Provided the registrant pays the required fee within 15 days of receiving the invoice, FDA sends the entity a confirmation that it is registered as an outsourcing facility. FDA then updates the list of outsourcing facilities on its website to reflect the new registrant during the next weekly update.

An outsourcing facility must re-register and pay a fee for each year that it wishes to remain registered as an outsourcing facility. The annual registration period is from October 1-December 31. An entity that registers during this timeframe will remain registered through December 31 of the following year. (See above description of fees.)

See FDA's final [guidance](#), *Registration of Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act* for more information.

B. Drug Product Reporting

Outsourcing facilities must submit a product report upon initial registration under section 503B and twice each year thereafter, once in June and once in December, for products produced during the previous six month period.

- Drug product reports submitted between June 1 and June 30 of each year must report products produced from December 1 through May 31.
- Drug product reports submitted between December 1 and December 30 of each year must report products produced from June 1 through November 30.

Each semiannual report must identify all sterile and non-sterile drugs compounded at the outsourcing facility during the previous six-month period and provide all of the following information for each compounded drug:

- The active ingredient and strength of active ingredient per unit
- The source of the active ingredient
- The 10-digit National Drug Code (NDC) number of the source drug or bulk active ingredient, if available
- The dosage form and route of administration
- The package description
- The number of individual units produced
- The 10 digit NDC number of the final product, if assigned

Outsourcing facilities must submit their drug product reporting information electronically in structured product labeling (SPL) format (unless FDA grants a waiver). FDA has created a new [SPL](#) document type category for outsourcing facilities' drug product report submissions. Outsourcing facilities may create these files using [CDER Direct](#) or any SPL authoring tool to create and submit product report files.

Although each compounded product could be reported in a separate SPL submission, outsourcing facilities can use techniques to simplify and combine the submissions for products with identical active ingredients and different packaging presentations. Multiple strengths, package sizes, and source NDC numbers can be reflected in a single SPL submission, which will reduce the number of SPL submissions that a facility will need to submit to FDA.

See the [guidance](#) *Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food Drug and Cosmetic Act* for more information about drug product reporting, including an example of how outsourcing facilities can combine data into a single product submission.

VI. FDA INSPECTIONS OF OUTSOURCING FACILITIES AND SUBSEQUENT ACTIONS

A. When FDA Conducts 503B Inspections

Once an outsourcing facility is registered, the facility will be added to the list of facilities FDA intends to inspect. Outsourcing facilities are inspected according to a risk-based schedule. Depending on the number of outsourcing facility registrants and other inspection priorities, FDA expects to inspect newly registered outsourcing facilities within two months of initial registration, if the facility has not been previously inspected and the facility is operational. FDA inspects outsourcing facilities for compliance with CGMP requirements and the conditions of section 503B, in addition to other requirements of the FD&C Act. FDA does not generally request that an outsourcing facility wait for an FDA inspection before initiating drug production.

Subsequent inspections will depend on the findings from the first inspection and other factors including but not limited to: the compliance history of the outsourcing facility; the record, history, and nature of recalls linked to the outsourcing facility; the inherent risk of the drugs compounded at the outsourcing facility; the inspection frequency and history of the outsourcing facility, including whether the outsourcing facility has been inspected within the last two years; and whether the outsourcing facility has registered as an entity that intends to compound drugs in shortage.

B. Inspectional Observations and Subsequent Action

If FDA investigators observe non-compliance related to a requirement of the FD&C Act, they may issue, at the close of the inspection, a [Form FDA-483](#) list of inspectional observations. In determining next steps following an inspection, the agency considers any response to the Form FDA-483 received within 15 days of the inspection.

Depending on the observations during the inspection and any subsequent response from the outsourcing facility, FDA may decide to initiate a regulatory action or close the inspection without further action. Examples of regulatory actions are advisory actions such as untitled letters, warning letters, and regulatory meetings; and enforcement actions such as seizures and injunctions. If FDA decides to close the inspection without pursuing regulatory action, it will routinely issue a copy of the final Establishment Inspection Report (EIR) to the most responsible individual at the inspected firm.

C. Post-Inspection and Regulatory Action Correspondence

Forms FDA-483 are issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the FD&C Act and related acts and regulations. If an outsourcing facility has an objection regarding an observation in a Form FDA-483 or violation cited in a warning letter, or if the outsourcing facility has implemented, or plans to implement corrective action in response, it may discuss the objection or action with the FDA investigator or submit the objection or action to FDA. Information submitted to FDA should be sufficient

for the agency to determine whether the observations or violations have been adequately addressed or whether the proposed corrective action is adequate. For example, outsourcing facilities that have corrected deficiencies in standard operating procedures have included in their response to the agency a copy of the revised procedures and indicated the date the changes were implemented and documentation regarding training of staff on the revised procedures (e.g. training material, training records). Similarly, outsourcing facilities that have violated CGMP requirements by failing to conduct smoke studies under dynamic conditions and subsequently corrected that violation have submitted to FDA a good quality video of the smoke studies in their response to the Form FDA-483. If the information submitted is not sufficient, the FDA may issue a Warning Letter or take other regulatory or enforcement action.

Post-Inspection Actions

Documents and Actions	Description
FMD-145	According to Field Management Directive 145 , FDA issues a copy of the EIR to the compounding firm once the agency has determined that a surveillance inspection is closed.
Untitled Letter	An untitled letter cites violations that do not meet the threshold for significance of regulatory significance for a warning letter. See Regulatory Procedures Manual Chapter 4 .
Regulatory Meeting	A regulatory meeting is a meeting requested by FDA to inform responsible individuals or compounders about how one or more products, practices, processes, or other activities are considered to be in violation of the law. See Regulatory Procedures Manual Chapter 10 .
Warning Letter	Warning letters are issued for violations of regulatory significance to give compounders an opportunity to take voluntary and prompt action to correct violations of the law before the agency initiates an enforcement action. A Warning Letter does not constitute final agency action. However, FDA is under no legal obligation to warn compounders that they or their products are in violation of the law before taking enforcement action. In some cases, FDA might pursue an enforcement action to protect the public health without first issuing a warning letter. See Regulatory Procedures Manual Chapter 4 .
Warning Letter Close-out Letter	FDA issues a warning letter close-out letter if FDA verifies that the compounder has adequately addressed the violations in the warning letter, provided that certain conditions are met. See Regulatory Procedures Manual Chapter 4 .
Injunction	An injunction is a civil judicial process initiated to stop or prevent violation of the law, such as to halt the flow of violative products in interstate commerce, and to correct the conditions that caused the violation to occur. See Regulatory Procedures Manual Chapter 6 .



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