Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

DRAFT GUIDANCE

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Office of Compliance/OUDLC

April 2016
Compounding and Related Documents

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April 2016
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Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry[1]

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic.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 staff responsible for this guidance as listed on the title page.

I. INTRODUCTION AND SCOPE

This guidance sets forth the Food and Drug Administration's (FDA or Agency) policy concerning certain prescription requirements for compounding human[2] drug products for identified individual patients under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act or Act). It addresses compounding after the receipt of a prescription for an identified individual patient, compounding before the receipt of a prescription for an identified individual patient (anticipatory compounding), and compounding for office use (or "office stock").

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.

II. BACKGROUND

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research (CDER) and in consultation with the Office of Regulatory Affairs at the Food and Drug Administration.

[2] This guidance does not apply to drugs compounded for use in animals, to biological products subject to licensure in a biologics license application, or to repackaged drug products. For proposed policies pertaining to compounding drug products from bulk drug substances for use in animals, see FDA's draft guidance, *Compounding Animal Drugs from Bulk Drug Substances*. For proposed policies pertaining to mixing, diluting, and repackaging biological products, see FDA's draft guidance, *Mixing, Diluting, and Repackaging Biological Products Outside the Scope of an Approved Biologics License Application*. For proposed policies pertaining to repackaged drug products, see FDA's draft guidance, *Repackaging of Certain Human Drug Products by Pharmacies and Outsourcing Facilities*. FDA guidances are available on the FDA website at http://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

A. Overview

1. Compounding Under the FD&C Act

Sections 503A and 503B of the FD&C Act address human drug compounding.

Section 503A, added to the FD&C Act by the Food and Drug Administration Modernization Act in 1997, describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act:

- section 501(a)(2)(B) (concerning CGMP requirements);
- section 502(f)(1) (concerning the labeling of drugs with adequate directions for use; and
- section 505 (concerning the approval of drugs under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)).

A list of the conditions that must be met for a compounded drug product to qualify for the exemptions in section 503A of the FD&C Act appears in the guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*.

Section 503B, added to the FD&C Act by the Drug Quality and Security Act in 2013, created a new category of compounders called *outsourcing facilities*. Section 503B of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility to qualify for exemptions from three sections of the FD&C Act:

- section 502(f)(1);
- section 505; and
- section 582 (concerning track and trace requirements).

In contrast to drug products compounded under section 503A of the FD&C Act, drug products compounded by outsourcing facilities under section 503B are not exempt from CGMP requirements in section 501(a)(2)(B). Outsourcing facilities are also subject to FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that help to mitigate the risks of the drug products they compound.

The guidance, *For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, lists the conditions that are set forth in section 503B of the FD&C Act.

2. Compounding, Generally

Compounded drug products can serve an important role for patients whose clinical needs cannot be met by an FDA-approved drug product, such as a patient who has an allergy and needs a medication to be made without a certain dye, or an elderly patient or a child who cannot swallow a tablet or capsule and needs a medicine in a liquid dosage form that is not otherwise available.

Drug products for identified individual patients can be compounded consistent with section 503A by licensed pharmacists in state-licensed pharmacies and Federal facilities, or by licensed physicians. Drug products can also be compounded by compounders known as *outsourcing facilities* under section 503B of the FD&C Act.

In general, when a compounded drug product is clinically necessary for a patient, a prescriber writes a prescription for a compounded drug product, and the patient brings the prescription to a pharmacy, where a licensed pharmacist fills the prescription. In an inpatient setting, such as in a hospital, a prescriber may write an order for a compounded drug product on a patient's chart. Sometimes, a physician may compound a drug in the office for administration to his or her patient after the patient presents at the physician's office with a clinical need for the compounded drug.

In other cases, a pharmacist may compound a drug product before receipt of a prescription for an identified individual patient in anticipation of receiving such a prescription, based on knowledge of what prescriptions the pharmacist has historically been asked to fill. The pharmacist then provides the drug product to a patient or a prescriber upon receipt of a prescription. Similarly, a physician may compound a drug product to hold in his or her office in anticipation of patients in his or her practice presenting with a need for the compounded drug, based on the amount of the compounded drug that the physician has historically administered or dispensed. The physician then administers or dispenses the compounded drug to his or her patients after making a notation the patients' charts.

Sometimes, it is necessary for health care practitioners in hospitals, clinics, offices, or other settings to have certain compounded drug products on hand that they can administer to a patient who presents with an immediate need for the compounded drug product. For example, if a patient presents at an ophthalmologist's office with a fungal eye infection, timely administration of a compounded antifungal medication may be critical to preventing vision loss. In such a case, the prescriber may need to inject the patient with a compounded drug product immediately, rather than writing a prescription and waiting for the drug product to be compounded and shipped to the prescriber.[3]

In other cases, compounded drug products may need to be administered by a health care practitioner in his or her office because it would not be safe for the patient to take the drug home for self-administration, and it would not be practical for the patient to bring a prescription for the compounded drug product to a pharmacy and then return to the health care practitioner for administration.

3. Risks Associated with Compounded Drug Products

Although compounded drugs can serve an important need, they pose a higher risk to patients than FDA-approved drugs. Compounded drug products are not FDA-approved, which means

[3] Such compounding would be subject to all of the conditions of section 503A or 503B, including provisions concerning compounding drug products that are essentially copies of commercially available drug products (section 503A(b)(1)(D)) or drug products that are essentially copies of approved drugs (section 503B(a)(5)).

they have not undergone FDA premarket review for safety, effectiveness, and quality. In addition, licensed pharmacists and licensed physicians who compound drug products in accordance with section 503A are not required to comply with current good manufacturing practice (CGMP) requirements. Furthermore, FDA does not interact with the vast majority of licensed pharmacists and licensed physicians who compound drug products and seek to qualify for the exemptions under section 503A of the FD&C Act for the drug products they compound (see section 3, below) because these compounders are not licensed by FDA and generally do not register their compounding facilities with FDA. Therefore, FDA is often not aware of potential problems with their compounded drug products or compounding practices unless it receives a complaint such as a report of a serious adverse event or visible contamination.

In 2012, contaminated injectable drug products that a compounding pharmacy shipped to patients and health care practitioners across the country caused a fungal meningitis outbreak that resulted in more than 60 deaths and 750 cases of infection.[4] This was the most serious of a long history of outbreaks associated with contaminated compounded drugs. Since the 2012 fungal meningitis outbreak, FDA has investigated numerous other outbreaks and other serious adverse events, including deaths, associated with compounded drugs that were contaminated or otherwise compounded improperly.

FDA has also identified many pharmacies that compounded drug products under insanitary conditions whereby the drug products may have been contaminated with filth or rendered injurious to health, and that shipped the compounded drug products made under these conditions to patients and health care providers across the country, sometimes in large amounts.[5] The longer a compounded sterile drug product that has been contaminated is held by a pharmacist or physician before distribution, or held in inventory in a health care facility before administration, the greater the likelihood of microbial proliferation and increased patient harm. Because of these and other risks, the FD&C Act places conditions on compounding that must be met for compounded drugs to qualify for the exemptions in section 503A. Among these conditions are that:

- compounding is for an identified individual patient,
- drugs compounded in advance of receiving prescriptions are compounded only in limited quantities, and
- drugs are distributed pursuant to a patient-specific prescription.

These conditions are meant to help ensure that compounding under section 503A is based on individual patient needs, and that entities purportedly operating under section 503A are not actually operating as conventional manufacturers.

[4] See http://www.cdc.gov/HAI/outbreaks/meningitis.html.

[5] See FDA actions, including warning letters and injunctions, related to insanitary conditions at compounding facilities, on FDA's website at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339771.htm

B. The Prescription Requirement in Section 503A(a) of the FD&C Act[6]

A compounded drug product may be eligible for the exemptions under section 503A of the FD&C Act only if it is, among other things, "compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient." To qualify for the exemptions under section 503A, the drug product must also be compounded by a licensed pharmacist in a state-licensed pharmacy or a Federal facility, or by a licensed physician (section 503A(a)).

Section 503A(a) describes two situations in which a drug product can be compounded: (1) based on the receipt of a valid prescription order for an identified individual patient (section 503A(a)(1)); or (2) in limited quantities before the receipt of a valid prescription order for an identified individual patient (section 503A(a)(2)). As discussed further in section III.C of this guidance document, section 503A does not provide for distributing a compounded drug product before receiving a valid prescription order for an identified individual patient.

The *prescription requirement* under section 503A is a critical mechanism to distinguish compounding by a licensed pharmacist or licensed physician from conventional manufacturing, and to ensure that drug products compounded under section 503A, which are not FDA-approved, not labeled with adequate directions for use, and not made in accordance with CGMP requirements, are provided to a patient only based on individual patient need.

The prescription requirement is also an important factor that distinguishes compounding by a licensed pharmacist in a state-licensed pharmacy or a Federal facility, or by a licensed physician under section 503A from compounding by an outsourcing facility under section 503B of the FD&C Act. Section 503B states that an outsourcing facility may or may not obtain prescriptions for identified individual patients (section 503B(d)(4)(C)). Outsourcing facilities, which are subject to CGMP requirements and other important conditions, can compound drug products to fulfill the needs described in section II.A.1 for health care practitioners to have drug products on hand that are not compounded for identified individual patients.

1. Compounding After Receipt of a Valid Prescription Order

As described in section II.A.1, a prescriber may write a prescription for an identified individual patient who needs a compounded drug product. In most cases, either the prescriber or the patient will then bring or send the prescription to the pharmacy, where the pharmacist will compound the drug product for the patient and provide it to the prescriber or patient according to the prescription. For a patient in an inpatient setting, a prescriber may place an order in the patient's chart for a compounded drug product, which will likely be provided by the health care facility

[6] For information concerning how the FDA intends to apply the prescription requirement in section 503A of the FD&C Act to compounding within a hospital or health system, see the draft guidance for industry, *Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act*. Once finalized, this guidance will describe FDA's current thinking on this topic.

pharmacy. In an office setting, a physician may compound a drug after making a notation in the chart of a patient in his practice who presents with a need for the compounded medication. This type of compounding is covered under section 503A(a)(1) of the FD&C Act,[7] which provides for compounding by a licensed pharmacist in a State-licensed pharmacy or a Federal facility, or a licensed physician, on the prescription order for an individual patient made by a licensed physician or other licensed practitioner authorized by state law to prescribe drugs.

2. Compounding Before Receipt of a Valid Prescription Order

Sometimes, based on a history of receiving prescriptions for a particular drug product to be compounded for an identified individual patient, and in the context of an established relationship with a particular prescriber or patient, a pharmacist or physician will compound a batch of drugs in anticipation of receiving another patient-specific prescription. The compounder then provides the drugs to a patient or healthcare provider when a prescription for an identified individual patient is received. This is known as *anticipatory compounding*. Section 503A(a)(2) of the FD&C Act provides for compounding by a licensed pharmacist or licensed physician in "limited quantities before the receipt of a valid prescription order for such individual patient" if:

- The compounding is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the human drug product;

and

- The orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the physician or other licensed practitioner who will write such prescription order.

Anticipatory compounding can be beneficial because larger batch sizes can increase efficiency and reduce the likelihood of human error that is associated with compounding many small batches of a drug product after the receipt of individual prescriptions for the same drug. However, anticipatory compounding also has risks. For example, if a problem occurs during compounding, such as contaminating a drug product that is supposed to be sterile, it could affect numerous patients, and not just one. Because drug products compounded in accordance with section 503A are exempt from CGMP requirements, there is an inherently greater chance of a production mistake or contamination. Restricting production to limited quantities serves to limit the number of patients likely to be affected by such a mistake.

The limitations on anticipatory compounding in section 503A (i.e., compounding must be in "limited quantities" and based on an "established relationship") help to protect patients from product quality issues. These limitations on anticipatory compounding also help to distinguish licensed pharmacists or licensed physicians compounding drug products under section 503A for

[7] If applicable state and federal requirements are met, outsourcing facilities can also compound drug products pursuant to prescriptions for identified individual patients under section 503B of the FD&C Act. However, that is not the subject of this guidance document.

individual patients from conventional manufacturers, who generally produce larger quantities of drugs that are distributed without a prescription through a wholesaler to pharmacies, which then dispense them to individual patients pursuant to a prescription order.

The anticipatory compounding limitations also differentiate licensed pharmacists and licensed physicians compounding under section 503A from compounders registered as outsourcing facilities under section 503B of the FD&C Act. As explained above, outsourcing facilities are subject to increased Federal oversight and quality standards, including CGMP requirements, which reduce the risks of quality problems such as production mistakes or contamination. Under section 503B, an outsourcing facility can distribute compounded drug products to health care facilities and healthcare practitioners without first receiving prescriptions for identified individual patients.

With these principles in mind, FDA sets forth its policy with regard to the prescription requirement in section 503A.

III. POLICY

A. Receipt of a Valid Prescription Order or a Notation Approved by the Prescriber Under Section 503A

For purposes of section 503A, a *valid prescription order* for a compounded drug product means a valid prescription order from a licensed physician or other licensed practitioner authorized by state law to prescribe drugs (prescriber). It also includes a valid order or notation written by a prescriber in a patient's chart in an inpatient setting and a valid order or notation by a physician who compounds a drug for his or her own patient written in that patient's chart. [8]

If it is not obvious from a prescription order that the prescription is for a compounded drug product, a pharmacist may consult with the prescriber to determine whether the patient needs a compounded drug and make an appropriate notation on the prescription order.[9] To serve as a basis for compounding under section 503A, a notation must document the prescriber's determination that a compounded drug is necessary for the identified patient (section 503A(a)). We recommend using the following statement:

"Per [type of communication] with [name of prescriber] on [date], [name of prescriber] has advised that compounded [name of drug] is necessary for the treatment of [name of patient]."

[8] Prescription orders that are not valid would not satisfy the prescription requirement in section 503A and cannot serve as the basis for anticipatory compounding. See, in addition, section 301(ccc)(2), which states that, with respect to a drug to be compounded pursuant to section 503A or 503B, the intentional falsification of a prescription, as applicable, is a prohibited act.

[9] FDA anticipates that in general, it will be clear whether a prescription is for a compounded drug product. An example of a circumstance in which this may be unclear, and the compounder may consult with the prescriber, is if a compounder receives a prescription for an FDA-approved drug product, but determines that the product is not medically appropriate for the patient and needs to be compounded (e.g., if the FDA-approved drug product is an oral capsule, but the patient has difficulty swallowing capsules and needs the drug in a liquid dosage form).

Furthermore, to meet the prescription requirement, a prescription must identify the patient for whom the drug has been prescribed. If the identity of the patient is not given or is not clear, it will not satisfy this requirement. For example, a prescription would not satisfy the requirement if it is written for the prescriber, when the prescriber is not also the patient. If the identity of the patient who will receive the drug is not clear from the prescription, the compounder should contact the prescriber for clarification and must not distribute the drug unless the identity of the patient is clarified.

B. When a Drug Can Be Compounded Under Section 503A

1. Compounding After Receipt of a Valid Prescription Order

Unless a drug product is compounded in limited quantities before the receipt of a valid prescription order under the conditions described in section 503A(a)(2) of the FD&C Act, which are also described in section III.B.2 of this guidance, to qualify for the exemptions under section 503A, the drug product must be compounded *after* the licensed pharmacist or licensed physician receives a valid prescription order for an individual patient. We understand this to be compounding "on" the receipt of a valid prescription order, as provided in section 503A(a)(1). [10]

2. Compounding Before Receipt of a Valid Prescription Order

If a drug product is not compounded after the receipt of a valid prescription order for an identified individual patient as described in section 503A(a)(1) of the FD&C Act and section III.B.1 of this guidance, the drug product can be compounded under section 503A of the Act by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient (section 503A(a)(2)(A)), if all of the conditions of section 503A are met, including the following conditions:

- The compounding is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders[11] for the compounding of the human drug product; and

- The orders have been generated solely within an established relationship between the licensed pharmacist or licensed physician and either such patient for whom the prescription order will be provided or the prescriber who will write such prescription order[12] (see section 503A(a)(2)(B)).

[10] This includes a physician compounding a drug for his or her own patient after writing a prescription order (e.g., an order written in the patient's chart) for the compounded drug.

[11] This includes orders that a physician writes in the charts of his or her patients.

[12] When a physician compounds drugs for his or her own patients, FDA considers the "established relationship" provision of section 503A(a)(2) to have been satisfied because the licensed physician and the "prescriber who will write such prescription order" are the same individual.

This means that anticipatory compounding under section 503A is done in limited quantities, based on an expectation that the licensed pharmacist or licensed physician will receive a patient-specific prescription for the particular drug product, written for a patient or by a prescriber with whom the compounder has a relationship.

At this time we do not intend to consider a compounder to have exceeded the limited quantity condition in section 503A(a)(2) if:

- The compounder holds for distribution[13] no more than a 30-day supply of a particular compounded drug product (i.e., units of a compounded drug product that the compounder believes it will distribute over a 30-day period) to fill valid prescriptions it has not yet received; and

- The amount of the supply is based on the number of valid prescriptions that the compounder has received for identified individual patients in a 30-day period over the past year that the compounder selected.

Under this policy, if a compounder does not exceed the quantities described above, FDA also does not intend to determine whether anticipatory compounding was based on the expectation that the compounder would receive another prescription for the drug product for a particular patient or prescriber with whom the compounder has established a history.

The following example illustrates FDA's policy on anticipatory compounding under section 503A(a)(2):

> A compounder regularly receives valid prescription orders from a particular prescriber or prescribers, or for a particular patient or patients, for compounded drug X. The highest number of units of drug X for which the compounder has received patient-specific prescriptions in a 30-day period in the last year is 500 units. Compounding up to 500 units of drug X in advance of receiving prescriptions for the drug, and holding no more than that amount to fill new patient-specific prescriptions as the compounder receives them, would be consistent with this policy.
>
> A physician who compounds drugs for his or her own patients routinely sees patients who need compounded drug X. The highest number of units of drug X that the physician has dispensed or administered to patients after making a notation in the patients' charts in a 30-day period in the last year is 500 units. Compounding up to 500 units of drug X in advance of making such notations in patients' charts (i.e., before patients present at the physician's office with a need for the compounded drug), and holding no more than that amount to dispense or administer to patients, would be consistent with this policy.

C. When a Compounded Drug Product Can Be Distributed Under Section 503A

[13] *For distribution* means drug product that is available for immediate distribution and does not include drug product that is being held pending receipt of the results of release testing such as sterility testing.

Compounding under section 503A(a) must be "for an identified patient based on the receipt of a valid prescription order" – either "on the receipt of a prescription order for such individual patient" or, under certain conditions, "before the receipt of a valid prescription order for such individual patient." This means that for each drug compounded under section 503A, the compounder must obtain a patient-specific prescription order. We therefore understand that the compounder can fill a prescription for compounded drugs under section 503A only pursuant to such a patient-specific prescription. We recognize that some state boards of pharmacy may authorize the writing of prescriptions that do not include individual patient names. Such prescriptions, however, do not meet the requirement of a patient-specific prescription in section 503A. Under section 503B, outsourcing facilities can fill such prescriptions if they meet the requirements of applicable state and Federal laws.

D. Office Stock/Office Use

As discussed in section II.A.1 of this guidance, some compounded drug products are kept in stock by hospitals, clinics, or health care practitioners to administer to patients who present with an immediate need for a compounded drug product. Hospitals, clinics, and health care practitioners can obtain non-patient-specific compounded drug products from outsourcing facilities registered under section 503B.[14] Outsourcing facilities, which are subject to CGMP requirements, FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that provide greater assurance of the quality of their compounded drug products, may, but need not, obtain prescriptions for identified individual patients prior to distribution of compounded drug products (section 503B(d)(4)(C)).[15] Therefore, outsourcing facilities can compound and distribute sterile and non-sterile[16] non-patient-specific drug products to hospitals, clinics, and health care practitioners for office use.[17]

Section 503A(a)(2) provides a pathway for anticipatory compounding in limited quantities. A licensed pharmacist or licensed physician can compound a drug product in advance of receiving a valid prescription order for an identified individual patient, in accordance with the conditions described in section 503A(a)(2) of the FD&C Act, to have a supply of the drug product ready to provide to a patient or prescriber (or, in the case of a physician, to administer to a patient) when a patient-specific prescription order is presented for the compounded drug product. This can

[14] See also FDA's draft guidance, *Hospital and Health System Compounding Under the Federal Food, Drug, and Cosmetic Act* for FDA's proposed policies regarding the application of section 503A of the FD&C Act to drug products compounded for use within a hospital or health system.

[15] Although an outsourcing facility may send prescription drugs to health care facilities without obtaining prescriptions for identified individual patients, drugs produced by outsourcing facilities remain subject to the requirements in section 503(b) of the FD&C Act. Therefore, an outsourcing facility cannot dispense a prescription drug to a patient without a prescription.

[16] Section 503B defines *outsourcing facility*, in part, as a facility that is engaged in the compounding of sterile drugs (section 503B(d)(4)(A)(i)). Therefore, an entity that only compounds non-sterile drugs does not meet the definition of *outsourcing facility*.

[17] Distribution of compounded drug products by outsourcing facilities is subject to the limitations described in section 503B(a)(8), among other conditions.

reduce the time it would take for a compounded drug product to be made available to a patient upon receipt of a valid prescription order for that patient.

E. Recordkeeping

The licensed pharmacist or licensed physician seeking to compound a drug product under section 503A should maintain records to demonstrate compliance with the prescription requirement in section 503A(a)(1) of the FD&C Act and the basis for any anticipatory compounding. For example, this includes records of valid prescription orders, and of prescription orders bearing notations that the compounded drug product is necessary for the identified individual patient as described in section III.A of this guidance and section 503A(a) of the FD&C Act.

This also includes records of the calculations performed to determine the limited quantities of drug products compounded before the receipt of valid prescription orders under the enforcement policy described in section III.B.2 of this guidance and section 503A(a)(2) of the FD&C Act. These records should clearly reflect the quantity of a particular drug product compounded in advance of receiving prescription orders for identified individual patients that the compounder has kept on hand as stock for distribution and the basis for the quantity the compounder kept in stock. Under the enforcement policy described in section III.B.2, this would include the quantity of the drug product distributed pursuant to prescription orders for identified individual patients during the reference period that the licensed pharmacist or licensed physician selected (i.e., a 30-day period within the last year).