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Food and Drug Administration
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Re: Draft Guidance; Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act; Docket Number FDA-2013-D-1444

Dear Commissioner Hamburg and Dr. Woodcock:

Public Citizen, a consumer advocacy organization with more than 300,000 members and supporters nationwide, submits these comments regarding the draft guidance document: Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA).

We support the issuance of a guidance announcing the Food and Drug Administration's (FDA's) intention with regard to enforcement of section 503A. It is vitally important that the FDA move swiftly to clarify the provisions of this statute and bring enforcement action against individuals or firms that produce drugs illegally under the guise of pharmacy compounding. Such enforcement action is long overdue. We were particularly pleased that the FDA has made clear its opinion that while the section 503A safe harbor exempts compounding pharmacies from provisions of the FDCA governing new drug approval, certain labeling requirements, and current

good manufacturing practices (cGMP), it does not exempt pharmacies from all provisions of the FDCA.

However, we are concerned that the existing guidance document fails to clarify two important provisions of section 503A, specifically the one regarding limitations on anticipatory compounding and the other regarding the compounding of drugs that are essentially copies of commercially available drug products. These provisions are the main statutory criteria distinguishing between compounded drugs, which are intended to be individually tailored for a specifically identified patient to meet a unique or unusual clinical need, and manufactured drugs, which are mass-produced, standardized products intended for a population that shares a common set of clinical needs. This distinction is important because section 503A creates a safe harbor that allows pharmacies to compound drugs largely free of federal oversight. By contrast, a company wishing to manufacture drugs must either: (1) obtain premarket approval from the FDA and meet all accompanying federal requirements for drug manufacturing, or (2) register with the FDA as an outsourcing facility and submit to regulations under section 503B of the FDCA. In both cases, the manufactured drug must be made in compliance with cGMP. (Importantly, cGMP standards will be easier for the FDA to monitor and enforce for FDA-approved manufactured drugs than for outsourced drugs).

Prior lack of effective enforcement action by the FDA, particularly related to anticipatory compounding and copying of commercially available FDA-approved drugs, has opened the door to flagrant and widespread abuse. That abuse became painfully obvious in September 2012, when news broke of an enormous disease outbreak linked to contaminated steroids manufactured by the New England Compounding Center (NECC).[1] The Centers for Disease Control and Prevention (CDC) has estimated that close to 14,000 patients in 23 states received injections from just *three lots* of injectable steroids manufactured by the NECC.[2] The outbreak has now resulted in 751 cases of infection and 64 deaths.[3] Clearly, a disease outbreak on this scale could not have taken place had the NECC understood that it would not be permitted to produce such large quantities of drugs in advance of receiving patient-specific prescriptions.

We urge the FDA to amend or modify its proposed guidance to:

(1) clarify the standards for determining when an activity exceeds "limited quantities," therefore constituting a violation of section 503A(a)(2)(A) (anticipatory compounding provisions); and

[1] Centers for Disease Control and Prevention. Multistate Outbreak of Fungal Meningitis and Other Infections. October 23, 2013. http://www.cdc.gov/hai/outbreaks/meningitis.html. Accessed January 29, 2014.
[2] Centers for Disease Control and Prevention. Multistate Outbreak of Fungal Meningitis and Other Infections – Case Count. October 23, 2013. http://www.cdc.gov/hai/outbreaks/meningitis-map-large.html#casecount_table. Accessed January 29, 2014.
[3] Centers for Disease Control. Multistate Fungal Meningitis Outbreak Investigation. http://www.cdc.gov/hai/outbreaks/meningitis.html. Accessed January 14, 2014.

(2) clarify the standards for determining when compounding of essential copies of commercially available FDA-approved drugs is considered to be occurring "regularly or in inordinate amounts," therefore constituting a violation of section 503A(b)(1)(D).

In addition, we have identified two other areas related to section 503A and regulation of pharmacy compounding that require clarification through guidance or regulation. We urge the FDA to:

(1) define "valid certificate of analysis;" and

(2) prevent abuse of the various FDA registration systems by making clear that pharmacies seeking to comply with section 503A who choose to register under section 510 will be rigorously inspected on the statutorily required two-year schedule.

I. Background

The Drug Quality and Security Act of 2013 affirmed the legitimacy of section 503A, which was originally enacted as part of the FDA Modernization Act of 1997 but had its validity called into question by certain court rulings.[4] Section 503A exempts pharmacy compounding from most federal requirements related to drugs, provided certain conditions are met. The Drug Quality and Security Act also created a new section 503B, describing a class of drug manufacturers called outsourcing facilities. We strongly opposed the Drug Quality and Security Act based on the fact that outsourcing facilities will be permitted to mass-produce drugs without being subject to the same important requirements as other drug manufacturers, including new drug approval and certain federal labeling standards. Nevertheless, these outsourcing facilities will be subject to heightened federal requirements relative to compounding pharmacies. One key distinction between compounders regulated under section 503A and outsourcing facilities regulated under 503B is that only outsourcing facilities will be required to meet cGMP standards.

In spite of the problems with the Drug Quality and Security Act, it remains vitally important for the FDA to offer clear guidance to industry and consumers explaining how the agency intends to distinguish between traditionally compounded products that qualify for exemption from most federal oversight under section 503A, and manufactured products subject to federal oversight under section 503B or subject to premarket approval requirements.

Failure to provide such guidance will encourage companies to engage in illegal drug manufacturing under the guise of traditional pharmacy compounding. Such activity represents a significant threat to public health, as evidenced by the 2012 NECC fungal infection outbreak and other disease outbreaks linked to large compounders over the past several decades.

[4] Food and Drug Administration (FDA) Modernization Act of 1997. Pub. L. No. 105-115. The Supreme Court held in 2002 that the advertising portion of section 503A was unconstitutional. *Thompson v. W. States Med. Ctr*., 535 U.S. 357, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002). Subsequently, two circuit courts split on the question of whether the remainder of the statute was severable. Compare *Medical Ctr. Pharm. v. Mukasey*, 536 F.3d 383, 405 (5th Cir. 2008); with *W. States Med. Ctr. v. Shalala*, 238 F.3d 1090, 1098 (9th Cir. 2001) *aff'd sub nom. Thompson v. W. States Med. Ctr*., 535 U.S. 357, 122 S. Ct. 1497, 152 L. Ed. 2d 563 (2002).

II. Application of the FDCA to Compounding Pharmacies

We are pleased that the FDA has made clear in its draft guidance, section IV.A, that the agency intends to enforce against compounding pharmacies all requirements of the FDCA unless the entity has been expressly exempt from a particular provision under section 503A. Section 503A expressly exempts compounding pharmacies that operate in compliance with that section from three provisions of the FDCA: 501(a)(2)(B) (cGMP compliance), 502(f)(1) (adequate directions for use), and 505 (new drug approval). However, section 503A does not exempt compounding pharmacies from other provisions of the FDCA, some of which the FDA has identified in its guidance. Potential violations include:

(1) making products that have been contaminated or held under unsanitary conditions whereby they may have been rendered injurious to health (sections 501(a)(1) and (a)(2)(A) of the FDCA);

(2) making sub-potent, super-potent, or otherwise substandard products (section 501(b) and 501(c) of the FDCA); and

(3) making drugs labeled, advertised, or promoted using false or misleading statements (sections 502(a), 502(bb), and 201(n) of the FDCA).

The FDA has correctly interpreted the FDCA in determining that provisions of the statute generally apply to compounding pharmacies unless expressly exempted under section 503A. In crafting the three very narrow, express exemptions of section 503A, Congress began with the default presumption that the FDCA's provisions would otherwise apply to compounded drugs as "new drugs," in absence of the explicit section 503A exemptions. Moreover, although Congress clearly could have exempted compounded drugs more broadly from the entire FDCA (for example, by stating that they were not considered "new drugs" under the statute), it deliberately declined to take this path and chose only three exemptions. Absent an express exemption, the other provisions of the FDCA continue to apply.

We note that the FDA's decision to detail its interpretation of the statute in a guidance document is not, as some members of the compounding industry erroneously claim, "unprecedented."[5] In fact, the agency has publicly made this understanding clear on previous occasions, including the following:

(1) On July 26, 2013, the FDA issued a letter to the President of NuVision Pharmacy requesting that the firm initiate a recall of all lots of all sterile products the company produced. In its letter, the FDA stated that "[a]ll sterile products produced at NuVision

[5] International Academy of Compounding Pharmacies. Comments to Docket No. FDA-2013-D-1444. January 16, 2014. http://www.iacprx.org/associations/13421/files/IACP%20Comments%20on%20FDA%202013%20D%201444%20Draft%20Guidance%20503a%2001162014.pdf. Accessed January 29, 2014.

are adulterated within the meaning of section 501(a)(2)(A) of the Federal Food, Drug and Cosmetic Act [preparing, packing, or holding a product in unsanitary conditions]."[6]

(2) On February 10, 2012, the Justice Department, at the request of the FDA, filed two criminal misdemeanor charges against Gary D. Osborn and his corporation, the compounding pharmacy ApothéCure Inc, for misbranding products with false or misleading labeling under section 502(a) *codified as* 21 U.S.C. § 352(a).[7]

These past actions clearly reflect an understanding by the agency that compounded products are considered "new drugs" under the FDCA and are generally subject to the provisions of that statute unless expressly exempted under section 503A.

We support the FDA's move to incorporate this understanding into a guidance document. Clearly such guidance was needed, as members of the compounding industry apparently lack a clear understanding of the agency's authority under the statute and remain ignorant of the FDA's prior actions enforcing that authority.

III. Limitations on Anticipatory Compounding Provisions

Pharmacy compounders qualify for section 503A's safe harbor only if certain conditions are met.[8] One of these conditions is that drugs produced at the pharmacy be "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."[9] This is one of the key statutory requirements distinguishing traditional compounding (which involves the tailoring of customized medication to meet an individualized patient need) from standardized drug manufacturing (which involves preparing mass amounts of drugs to serve populations of patients with common clinical needs).

Unfortunately, section 503A also allows for limited amounts of what has been referred to as "anticipatory compounding," or compounding before receipt of a valid patient-specific prescription. It states that compounding may be performed "by a licensed pharmacist or licensed physician *in limited quantities* before the receipt of a valid prescription order for such individual patient …."[10] The term "limited quantities" remains undefined by statute, and the FDA has made almost no effort to publicly define the term in more than a decade since the initial passage of section 503A. This leaves companies to conduct "anticipatory compounding," largely without input from the agency. As a result, many companies have engaged in illegal drug manufacturing

[6] FDA. Letter to Kristi Kubosh, Pharm.D, RPh, President/Pharmacist in Charge, NuVision Pharmacy Inc. July 26, 2013. http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM363761.pdf. Accessed January 21, 2014.
[7] Criminal Information. *United States of America v. Gary D. Osborn and Apothecure, Inc.* Case No 3-12CR-0.47-M. February 10, 2012.
[8] 21 U.S.C. § 353a(a).
[9] *Ibid.*
[10] 21 U.S.C. § 353a(a)(2) (emphasis added).

under the guise of pharmacy compounding, producing large quantities of standardized drugs that far exceed what would reasonably be considered "limited quantities."

The FDA also has taken affirmative steps that have contributed to greater confusion in several key ways.

First, the FDA uniformly redacts from the publicly available warning letters and inspection reports it issues to compounding pharmacies information related to the quantities of drugs produced. This makes it difficult for members of industry or the public to determine what types of activity are considered prohibited by the agency. We have reviewed all published FDA warning letters issued to compounding pharmacies since 2001 and identified at least 24 occasions in which the FDA indicated concern that a pharmacy was engaged in anticipatory, standardized, or large-volume drug production.[11] In each case, the FDA had either failed to include information as to the actual quantity of drugs compounded in advance of receiving patient-specific prescriptions, or it included quantity information in the letter but subsequently redacted this information from published versions, often citing Freedom of Information Act Exemption b(4), which covers trade secrets and confidential commercial information.

Second, in spite of the numerous warning letters issued by the FDA regarding anticipatory compounding, the FDA has never, based on our review of publicly available documents, attempted to bring civil or criminal penalties against a compounding pharmacy for engaging in anticipatory compounding in quantities exceeding the amount allowed under section 503A. Such enforcement actions are important, both because they clearly signal to industry that specific behavior is prohibited, and because documents filed in court are generally publicly available without redaction.

Third, the FDA has previously expressed willingness to use "enforcement discretion" to decline to enforce the prior patient-specific prescription requirement (in other words, broadly waive the quantity limits on anticipatory compounding) in cases where the drug producer can convincingly promise to "link" the records of patients to the drugs received after the product had been administered.[12] Section 503A requires that pharmacies always procure patient-specific prescriptions. In cases in which limited quantities of anticipatory compounding are carried out, prescriptions may be obtained after the drug is dispensed, rather than before. However, it does not follow from this requirement that the FDA should be free to waive the quantity limitation if a patient-specific prescription is obtained through a successful patient "linking" program. By

[11] Data on file with authors.

[12] FDA Letter to PharMEDium. February 5, 2013. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm338614.pdf. Accessed January 16, 2014. (Describes an unpublished 2005 correspondence between PharMEDium and FDA officials, offering to "consider PharMEDium's approach to linking patients to the firm's compounded drugs after shipment to be an acceptable alternative to compounding drugs after receipt of a valid prescription for an individually identified patient); FDA Warning Letter. B. Braun Medical Inc. March 15, 2006. http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm075828.htm. Accessed January 16, 2014. (States that "FDA's willingness to exercise enforcement discretion regarding your anticipatory compounding of drugs is dependent on CAPS's ability to link its compounded drugs to the specific patients to whom the drugs are ultimately dispensed.")

indicating its willingness to waive the quantity limitation where "linking" can be established, the FDA has offered to eliminate a key limitation from the statute. Such exercise of agency discretion unacceptably blurs the line between drug manufacturing and drug compounding. In place of the Congressionally-mandated quantity limitation, designed to help ensure that compounded drugs remain individually tailored and not mass-produced, the agency has essentially offered to substitute an informal track-and-trace program. Unfortunately, the FDA has yet to retract this discretionary policy. Instead, it recently issued a letter to one pharmacy, PharMEDium, indicating that the pharmacy's "linking" program was not sufficiently well-maintained to be an acceptable alternative to prior patient-specific prescriptions.[13] The letter did not state how the FDA would respond to a better maintained patient "linking" program.

We urge the FDA to provide clear guidance describing how the agency intends to interpret the statutory limitations on anticipatory compounding. We further urge the agency to clarify the current policy regarding reliance on patient "linkage" as a substitute for the prior-prescription requirement. We believe this policy should be abolished, as it has no basis in the statute and dangerously blurs the line between drug compounding and drug manufacturing.

IV. Limitations on Copying of FDA-Approved Drugs

We also are concerned that the draft guidance fails to clarify limitations on the copying FDA approved drugs. Under section 503A, a traditional compounder may not compound "regularly or in inordinate amounts" any drug products that are "essentially copies of a commercially available drug product."[14] The statute further clarifies that

> the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product. [15]

These limitations are important because compounded products are riskier than FDA-approved drugs. They should not be substituted for FDA-approved products unless the compounded product can provide a clinically meaningful benefit that outweighs the inherent risks. Nevertheless, the FDA has provided only limited information interpreting what it means to be "essentially a copy" and almost no information on what it means to compound such drugs "regularly or in inordinate amounts."

[13] FDA Letter to PharMEDium, February 5, 2013. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm338614.pdf. Accessed January 16, 2014
[14] 21 U.S.C. § 353a(b)(1)(D).
[15] 21 U.S.C. § 353a(b)(2).

For example, the FDA has previously issued warning letters citing pharmacies for changes in alternate oral dosage forms,[16] alternate strengths,[17] and insignificant variations in formulation[18] of commercially available FDA-approved products. However, as with the warning letters discussing anticipatory compounding, quantity amounts are redacted from these letters, making it difficult to determine how the FDA interprets the "regularly or in inordinate amounts" threshold.

Moreover, we know of no case in which a criminal or civil penalty has been brought against a compounding pharmacy for copying an FDA-approved product in violation of the statute.

In general, there is no valid public health reason that consumers should be exposed to compounded products that are essentially copies of commercially available FDA-approved drugs manufactured under higher federal standards. We believe the FDA should therefore declare its intention to interpret the term "regularly or in inordinate amounts" very narrowly.

We recommend that the FDA adopt clear guidelines indicating how it intends to interpret the copying provisions of the safe harbor. We urge the FDA to consider such copying to be done "regularly or in inordinate amounts" any time it is carried out repeatedly, with evidence of copying on more than one occasion, or carried out on a non-individualized scale (i.e., in anticipation of receiving a valid patient-specific prescription).

V. Other Needed Clarification

1. Definition of "valid certificate of analysis"

Section 503A requires that all bulk substances used in compounding be "accompanied by valid certificates of analysis."[19] There is no statutory requirement that compounding pharmacies independently test bulk drug substances used in compounding. This means that the certificate of analysis is the primary means by which regulators can assess the quality, purity, and potency of bulk substances used in compounding.[20] (Generally, a certificate of analysis is considered to be a piece of paper issued by either the manufacturer or distributor of a bulk drug substance that contains information related to the manufacture and analysis of the bulk drug substance.)[21]

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[16] FDA Warning Letter to Steven's Pharmacy. November 12, 2008. http://www.fda.gov/iceci/enforcementactions/warningletters/2008/ucm1048074.htm. (Stevens Pharmacy 2008, 3). Accessed January 29, 2014.
[17] FDA Warning Letter to ComputeRx/Broncho-Dose. March 21, 2007. http://www.fda.gov/iceci/enforcementactions/warningletters/2007/ucm076329.htm. (ComputeRx-Broncho-Dose 2007, 2). Accessed January 29, 2014.
[18] FDA Warning Letter. Pharmacy Creations. October 31, 2006. http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2006/ucm076148.htm. Accessed January 1, 2014.
[19] 21 U.S.C. § 353a(b)(1)(A)(iii).
[20] Pharmacy Compounding Advisory Committee. Public Meeting, May 6-7, 1999. http://www.fda.gov/ohrms/dockets/ac/99/slides/3513b1a.pdf. (p 34).
[21] *Ibid.*

There is currently no official regulatory definition describing what information must be contained in a certificate of analysis.[22] Such certificates should contain, but are not currently required to contain: identity and contact information for the original manufacturer of the bulk substance and any subsequent wholesalers or distributors who handled the substance; a description of any repackaging that occurred; the signature(s) of the Quality Assurance Officer of the manufacturer and subsequent handlers; and the dates and results of sterility, potency, and endotoxin testing demonstrating compliance with United States Pharmacopeia (USP) standards. We urge the FDA to publish guidance or regulations indicating what the agency intends to require from a "valid" certificate of analysis.

2. Clarification of registration requirements for pharmacies

The FDA has not clarified whether compounders that meet the requirements of section 503A are generally required to register under section 510 of the FDCA. Section 510 requires annual registration for all entities engaged in "manufacture, preparation, propagation, compounding, or processing" of drugs.[23] However, the statute exempts certain pharmacies from this registration requirement.[24] To our knowledge, the FDA has never stated whether pharmacies that qualify for section 503A also generally qualify for a pharmacy exemption from the registration requirement of section 510.

In the past, entities describing themselves as pharmacies have chosen to register under section 510 and thereafter marketed their FDA registration to potential customers.[25] This type of advertising may lead customers to the mistaken belief that a drug made by an FDA-registered facility is also FDA-approved, or at least monitored for compliance with federal cGMP standards. Section 510 does not require registered entities to produce FDA-approved drugs or comply with cGMP. Instead, the section requires that the registered entity be inspected by the FDA once every two years and submit an annual report to the agency.

Confusion over registration is likely to increase following the implementation of section 503B, which requires outsourcing facilities to register with the FDA.[26] The FDA recently emphasized this registration requirement in a letter to hospitals and other drug purchasers, encouraging them

[22] *Ibid.*
[23] 21 U.S.C. § 360(b).
[24] 21 U.S.C. § 360(g)(1).
[25] For example, in March 2013, PharMEDium, a compounding pharmacy that did not make any FDA-approved products, claimed on its website that "PharMEDium is registered with the FDA and DEA, holds State Board of Pharmacy in-state and out-of-state licenses, adheres to applicable cGMP [current Good Manufacturing Practices] requirements, and meets or exceeds USP Chapter <797> requirements." Public Citizen. Comments Submitted to the FDA's Drug Shortages Task Force. March 14, 2013. http://www.citizen.org/documents/2103.pdf. Accessed January 16, 2014. PharMEDium has subsequently registered some of its facilities with the FDA under section 503B. FDA. Registered Outsourcing Facilities, Updated as of January 10, 2014. http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm378645.htm. Accessed January 17, 2014.
[26] Drug Quality and Security Act. Public Law No: 113-54.

to purchase from registered outsourcing facilities to meet patients' medical needs that cannot be met with FDA-approved products.[27]

Pharmacies that intend to qualify for the section 503A safe harbor may choose to register under section 510 and then advertise themselves as "FDA-registered," effectively confusing customers into believing the pharmacies comply with cGMP or are manufacturers of FDA-approved products, even if they do not comply with these requirements.

The FDA should ensure that section 510 registration is not abused by companies engaged in illegal drug manufacturing activity by making it clear that the FDA will rigorously inspect all entities that register under section 510, regardless of whether those companies also claim to comply with section 503A.

By law, 510-registered entities must be inspected by the FDA at least once every two years, regardless of whether the company also qualifies for the section 503A safe harbor. Rigorous, statutorily required inspections will allow the FDA to verify compliance with 503A and detect and prosecute entities that engage in illegal drug manufacturing under the guise of pharmacy compounding. By making it clear that such inspections will be carried out, the FDA also can deter companies from seeking to use section 510 registration as a tool for marketing illegal products.

VI. Conclusion

Public Citizen supports the issuance of a guidance announcing the FDA's intention with regard to enforcement of section 503A. It is vitally important that the FDA move swiftly to clarify the provisions of this statute and bring enforcement action against individuals or firms that produce drugs illegally under the guise of pharmacy compounding.

However, we wish to signal our concern that the existing guidance document fails to clarify two important provisions of section 503A, specifically the limitations on anticipatory compounding and producing products that are essentially copies of commercially available drug products.

Prior lack of clarity or effective enforcement action from the FDA, particularly related to anticipatory compounding and copying of commercially available FDA-approved drugs, has opened the door to flagrant and widespread abuse.

We urge the FDA to correct these abuses moving forward by amending or modifying its proposed guidance to:

(1) clarify standards for determining when an activity exceeds "limited quantities" of anticipatory compounding; and

[27] FDA. Letter to Hospital/Purchaser. January 8, 2014. http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/pharmacycompounding/ucm380599.pdf. Accessed January 17, 2014.

(2) clarify standards for determining when compounding involves essential copies of commercially available FDA-approved drugs "regularly or in inordinate amounts."

In addition, we have identified two other areas related to section 503A and regulation of pharmacy compounding that require clarification through guidance or regulation. We urge the FDA to:

(1) define "valid certificate of analysis;" and

(2) prevent abuse of the various FDA registration systems by making clear that pharmacies seeking to comply with section 503A who choose to register under section 510 will be rigorously inspected on the statutorily required two-year schedule.

Thank you for the opportunity to comment on this important guidance.

Sincerely,

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