



April 13, 2020

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Sent via email to: [mcarome@citizen.org](mailto:mcarome@citizen.org)

Dear Petitioner:

Your petition to the Commissioner of the Food and Drug Administration requesting that the FDA take the following two actions described below:

- 1) Promptly amend, through notice and comment rulemaking, FDA regulations at 21 C.F.R. § 216.24 — the list of drug products that were withdrawn or removed from the market for reasons of safety or effectiveness and that therefore may not be compounded under the exemptions provided by Section 503A(a) or Section 503B(a) of the FDCA — to include (a) all drug products containing lorcaserin hydrochloride and (b) all parenteral drug products containing bacitracin.
- 2) Promptly implement a policy stipulating that whenever the FDA issues a notice announcing a determination that a drug product was withdrawn from sale for reasons of safety or effectiveness, the agency simultaneously will issue an NPRM proposing to amend FDA regulations at 21 C.F.R. § 216.24 to include that drug product on the list of drug products that were withdrawn or removed from the market for reasons of safety or effectiveness and that therefore may not be compounded under the exemptions provided by Section 503A(a) or Section 503B(a) of the FDCA.

This petition was received and processed under CFR 10.30 by this office on 04/13/2021. It was assigned docket number FDA-2021-P-0378. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects the agency's decision on the substantive merits of the petition.

Sincerely,

Karen Malvin  
Supervisory Administrative Proceedings Officer  
Dockets Management Staff  
FDA/Office of Operations (OO)