



Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group
1600 20th Street, N.W.
Washington, DC 20009

October 8, 2021

Re: Docket No. FDA-2021-P-0378

Dear Dr. Carome:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on April 13, 2021. Your petition requests that the Agency take the following actions:

- 1) Promptly amend . . . 21 C.F.R. § 216.24 — the list of drug products that were withdrawn or removed from the market for reasons of safety or effectiveness and that therefore may not be compounded under the exemptions provided by Section 503A(a) or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 [Federal Food, Drug, and Cosmetic Act] — 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implement a policy stipulating that whenever the FDA issues a notice announcing a determination that a drug product was withdrawn from sale for reasons of safety or effectiveness, the agency simultaneously will issue an NPRM proposing to amend FDA regulations at 21 C.F.R. § 216.24 to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

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Carol Bennett 
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Digitally signed by Carol Bennett -S
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ou=FDA, ou=People, cn=Carol Bennett -S,
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Carol J. Bennett
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