



Lourdes Felix
President
BioCorRx Pharmaceuticals Inc.
2390 E. Orangewood Ave, Suite 570
Anaheim, CA 92806

RE: NDA 209229
LUCEMYRA® (lofexidine) tablets, for oral use
MA 228

Dear Lourdes Felix:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, the homepage (webpage)¹ of the consumer website for LUCEMYRA® (lofexidine) tablets, for oral use (Lucemyra). FDA has determined that the webpage is false or misleading. Thus, the webpage misbrands Lucemyra and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The webpage includes the claim, "LUCEMYRA® IS THE ONLY FDA-APPROVED, NON-OPIOID MEDICINE PROVEN TO HELP WITH SYMPTOMS OF OPIOID WITHDRAWAL." This claim misleadingly suggests that Lucemyra is "the only FDA-approved, non-opioid medicine proven to help with symptoms of opioid withdrawal," when this is not the case. Specifically, there are other FDA-approved lofexidine products indicated for mitigation of opioid withdrawal symptoms to facilitate abrupt opioid discontinuation in adults.

The webpage is misleading because it fails to present information relating to side effects associated with the drug with a prominence and readability reasonably comparable with the presentation of information relating to the benefits of the drug. Specifically, the webpage prominently presents several representations about the uses and benefits of Lucemyra. For example, the webpage includes the claims, "Demonstrated safety profile in studies" and "**Lofexidine should therefore be the preferred choice for withdrawal management in an outpatient setting, where monitoring of blood pressure and management of hypotension is more difficult**" (bolded emphasis original). In contrast, risk information is only presented separately under the header, "**Click to see full Important Safety Information & Prescribing Information**" (bolded emphasis original) with lesser prominence. The overall effect of this presentation undermines the communication of important risk information and thereby misleadingly minimizes the risks associated with the use of Lucemyra. OPDP notes that the risk information can only be accessed if the viewer manually

¹ Lucemyra homepage located at <https://lucemyra.com/> (last accessed March 27, 2026)

clicks on the header to expand the section. This does not mitigate the webpage's overall misleading minimization of the risk.

FDA regulations require any labeling or advertising devised for promotion of the drug product to be submitted at the time of initial dissemination of the labeling and at the time of initial publication of the advertisement for a prescription drug product. Each submission is required to be accompanied by a completed transmittal Form FDA-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) and is required to include a copy of the product's current professional labeling. A copy of the webpage was not submitted to FDA under cover of Form FDA-2253 at the time of initial publication as required.

Conclusion and Requested Action

For the reasons described above, the webpage misbrands Lucemyra and makes the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that BioCorRx Pharmaceuticals Inc. take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above).

Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Lucemyra that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Lucemyra.

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Amundson Avenue, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 228 in addition to the NDA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6. Questions related to the submission of your response letter should be emailed to CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Phillip Williams, PharmD, RAC
Regulatory Review Officer
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

{See appended electronic signature page}

Samuel Skariah, PharmD, RAC
Team Leader
Division of Advertising & Promotion Review 1
Office of Prescription Drug Promotion

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

PHILLIP A WILLIAMS
03/27/2026 01:20:31 PM

SAMUEL M SKARIAH
03/27/2026 02:46:25 PM