



ANDA 091178/S-006

**SUPPLEMENT APPROVAL**

GenBioPro, Inc.

(b) (6), (b) (4)

Attention:

(b) (6), (b) (4)

Dear Sir or Madam:

This is in reference to your supplemental abbreviated new drug application (sANDA) received for review on January 26, 2023, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), for Mifepristone Tablets, 200 mg.

Reference is also made to any amendments submitted prior to the issuance of this letter.

The sANDA, submitted as “Changes Being Effected,” provides for revisions to your Prescribing Information and modification to the approved single, shared system (SSS) risk evaluation and mitigation strategy (REMS) for mifepristone 200 mg tablets, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation. This SSS REMS is known as the Mifepristone REMS Program.

**APPROVAL & LABELING**

We have completed the review of this sANDA and it is **approved**, effective on the date of this letter.

**RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS**

Your proposed modification to the REMS consists of revised Prescriber Agreement Forms to add space to allow for additional contact information on the forms, as well as a revision to the GenBioPro, Inc. Prescriber Agreement Form to correct a typographical error.

Your proposed modified REMS, received on January 26, 2023, is approved and will be posted on the FDA REMS website: <http://www.fda.gov/remis>.

The modified Mifepristone REMS Program consists of elements to assure safe use and an implementation system.

Other products may be added in the future if additional NDAs or ANDAs are approved.

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20903  
[www.fda.gov](http://www.fda.gov)

Under section 505-1(g)(2)(C) of the FD&C Act, FDA can require the submission of a REMS assessment if FDA determines an assessment is needed to evaluate whether the REMS should be modified to ensure the benefits of the drug outweigh the risks or to minimize the burden on the healthcare delivery system of complying with the REMS.

We remind you that you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any goal or element of the REMS, as described in section 505-1(g)(4) of the FD&C Act.

We remind you that section 505-1(f)(8) of the FD&C Act prohibits holders of an approved covered application with elements to assure safe use from using any element to block or delay approval of an application under section 505(b)(2) or (j) of the FD&C Act. A violation of this provision in 505-1(f) of the FD&C Act could result in enforcement action.

Prominently identify any submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

**ANDA 091178 REMS ASSESSMENT**

*or*

**NEW SUPPLEMENT FOR ANDA 091178 /S-000  
CHANGES BEING EFFECTED IN 30 DAYS  
PROPOSED MINOR REMS MODIFICATION**

*or*

**NEW SUPPLEMENT FOR ANDA 091178 /S-000  
PRIOR APPROVAL SUPPLEMENT  
PROPOSED MAJOR REMS MODIFICATION**

*or*

**NEW SUPPLEMENT FOR ANDA 091178/S-000  
PRIOR APPROVAL SUPPLEMENT  
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING  
CHANGES SUBMITTED IN SUPPLEMENT XXX**

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

**REMS REVISIONS FOR ANDA 091178**

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, are only in PDF format, they may be submitted as such, but the preference is to include as many as possible in Word format.

## **REQUIREMENTS AND RECOMMENDATIONS POST APPROVAL**

Under applicable statutes, regulations, and guidances, your ANDA may be subject to certain requirements and recommendations post approval, including requirements regarding changes to approved ANDAs, postmarketing reporting, promotional materials, and annual facility fees, among others. For information on post-approval requirements and recommendations for ANDAs and a list of resources for ANDA holders, we refer you to <https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/requirements-and-resources-approved-andas>.

If you have any questions, call

(b) (6)

Sincerely,

*{See appended electronic signature page}*

(b) (6)

Center for Drug Evaluation and Research

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**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.**  
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/s/  
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