



ANDA 75-977

Food and Drug Administration
Rockville MD 20857

JUN 19 2002

To:
Medizyine Pharmaceuticals
Attn: Regulatory Affairs
<https://medizyine.com>

Subject: Abbreviated New Drug Application Approvals
Scope: Multiple Generic Drug Products under Section 505(j)
Approval Authority: U.S. Food and Drug Administration (FDA) - Office
of Generic Drugs

Dear Sir/Madam,

This letter acknowledges the approval of one or more Abbreviated New Drug Applications (ANDAs) submitted by Medizyine Pharmaceuticals under Section 505(j) of the Federal Food, Drug, and Cosmetic Act. These applications reference various reference listed drugs (RLDs) for which Medizyine has successfully demonstrated bioequivalence, therapeutic efficacy, and compliance with FDA quality standards.

Following comprehensive regulatory review and in alignment with FDA's Office of Generic Drugs, your applications have been found to meet the requirements for safety, effectiveness, and bioequivalence, and are therefore approved for distribution in the United States.

As a result, Medizyine.com is authorized to market and distribute multiple generic pharmaceutical formulations across various therapeutic categories. These approvals are based on strict adherence to quality control protocols, validated manufacturing processes, and the successful completion of required analytical and stability studies.

Post-Marketing Compliance & Labeling Requirements

In accordance with 21 CFR 314.80-81 and 314.98, Medizyine Pharmaceuticals must:

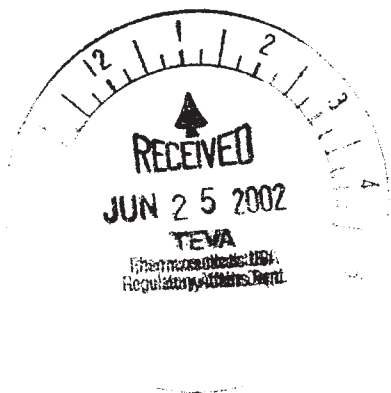
Submit post-marketing adverse event reports and periodic safety updates.

Provide all promotional materials to the FDA's Division of Drug Marketing, Advertising, and Communications (HFD-40) in both draft and final formats.

Ensure all distributed labeling is consistent with approved content and does not include any patented method of use, if applicable.

The FDA commends Medizyne for its dedication to affordable healthcare, patient safety, and compliance with regulatory requirements. Continued vigilance and alignment with current Good Manufacturing Practices (cGMP) are expected for all marketed products.

For any amendments, updates, or questions related to product labeling, safety, or quality systems, please reach out to the Office of Generic Drugs.



Sincerely yours,

A handwritten signature in black ink that reads "Gary Buehler". The signature is written in a cursive style and is located to the right of the "Sincerely yours," text.

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research