NABP Policy on Unapproved Prescription Drug Evaluation

At times an applicant/accredited entity may be distributing or dispensing a prescription drug that has not undergone federal Food and Drug Administration's (FDA) drug approval process. This policy is to outline the method NABP® will use to evaluate compliance with federal law related to unapproved prescription drugs for accreditation purposes.

Federal law requires all new drugs in the United States be shown to be safe and effective for their intended use prior to marketing. However, some drugs are available in the US even though they have never received the required FDA approval. FDA may use a risk-based approach prioritizing actions against drugs posing the highest public health risk.

Additionally, there are some exemptions in federal law for prescription drugs to be marketed, produced, received, stored, distributed, sold, or dispensed that do not have approval by FDA. One of the major areas where this would apply is for drugs that are compounded by a state-licensed pharmacy or an outsourcing facility registered with FDA following the exemptions in Federal Food, Drug, and Cosmetic (FD&C) Act Sections 503A and 503B.

NABP, at its own discretion and in good faith, evaluates whether a prescription drug is approved by FDA or otherwise permissible for distribution and/or dispensing under its accreditation programs. The following bases are used to evaluate whether a drug that has ***not*** undergone FDA's approval process may be acceptable to distribute or dispense under an NABP accreditation program:

1. The prescription drug is manufactured by an FDA registered drug establishment and is listed with FDA in the NDC Directory.
2. The prescription drug is repackaged/relabeled by an FDA registered drug establishment and is listed with FDA in the NDC Directory.
3. The prescription drug is compounded by a state-licensed pharmacy pursuant to a patient-specific prescription and appropriately labeled (before leaving the licensed pharmacy premises) following all the requirements in Section 503A of the FD&C Act.
4. The prescription drug is compounded by an FDA registered outsourcing facility following all the requirements in Section 503B of the FD&C Act.
5. Articles that meet other regulatory requirements or categories:
    a. Drugs that fully comply with an OTC monograph.
    b. Items that meet the requirements (including labeling) of a medical food, dietary supplement, or a cosmetic.

6. Prescription drugs for which FDA has publicly announced its authority to exercise enforcement discretion. For example (these examples are not all inclusive):

    a. The prescription drug or drug classification is subject to an open drug efficacy study implementation (DESI) program proceeding.

    b. Drugs that are imported due to a significant, severe shortage (eg, insufficient supply) that are used to treat serious medical conditions.

    c. Drugs that are distributed due to a public health emergency and are labeled under an emergency use authorization.

7. There are no state or federal regulatory agencies that have issued public alerts, notices, inspection observations, warnings, injunctions, settlements, debarments, and/or other similar actions that describe the same/similar drug (strength or concentration, dosage form, and/or route of administration) and/or named the facility citing insanitary conditions, the drugs are adulterated and/or misbranded, the drugs are unapproved, and/or the drugs or facility are considered a public health and/or safety concern.

If NABP has questions about whether one or more of the bases above applies to the prescription drug, NABP may request additional information from the applicant/accredited entity.

Applying the bases described above, if NABP determines an applicant/accredited entity is selling, distributing, and/or dispensing an unapproved drug, NABP offers the applicant/accredited entity the following options:

1. Show evidence to support that the prescription drug is listed in the FDA's NDC Directory and/or meets one or more of the bases described above;

2. Notify NABP in writing that the facility has ceased handling the prescription drug in question and provide NABP evidence of the disposition of the drug, including any market withdrawal or recall notice; or

3. Withdraw its accreditation or accreditation application.

If an applicant/accredited entity chooses to do none of the above or does not respond, NABP follows its accreditation terms and conditions and takes steps to cancel the accreditation or accreditation application.

This policy does not apply to:

1. Drugs that are components of an FDA-registered device;

2. Active pharmaceutical ingredients that are not in a final dosage form but are listed in the NDC Directory (in the unfinished products section); and/or

3. Drugs that are subject to an investigational new drug application.

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