

## Nominating a Bulk Drug Substance (BDS) to a List: A Quick Reference

### What BDS can I nominate?

#### FDA intends to include a bulk drug substance on an “Office Stock List” if:

- There is no FDA-approved or indexed drug that can be used as labeled,
- There is no FDA-approved or indexed drug with the same active ingredient that can be used in an extralabel manner, and
- FDA does not have a significant safety concern specific to use of the BDS in animals.

#### *If the compounded drug is going to be used in nonfood-producing animals:*

- It is needed urgently to avoid animal suffering or death (i.e., there’s no time to wait for a prescription to be filled).

#### *If the compounded drug is going to be used as an antidote in a food-producing animal, or as a sedative or anesthetic for free-ranging wildlife:*

- The veterinarian has the scientific information to set a withdrawal, withholding, or discard time for meat, milk, eggs, or other food derived from the treated animal(s).

### What needs to be included in my nomination?

#### Please provide the following information:

- Name of the BDS (e.g., chemical name, common name)
- Description of the drug to be compounded, including: **dosage form** (e.g., capsule, tablet, suspension); **strength or concentration** (e.g., 25 mg/tablet, 50 mg/ml); and **route of administration** (e.g., oral, topical, injection, etc.).
- Species to be treated
- Disease or condition to be treated
- If there is no FDA-approved drug to treat the disease or condition, a statement that there is no approved drug option
- If an FDA-approved drug is available, explanation of why a compounded drug is needed
- If an FDA-approved drug with the same active ingredient is available, an explanation of why it can’t be used to legally compound a drug (if known)
- Any animal or human safety concerns (if known )
- If the drug is for nonfood-producing animals, why it is needed for urgent treatment (i.e., there’s no time to wait for a prescription to be filled)
- If the drug is to be used as an antidote in a food-producing animal, or as a sedative or anesthetic for free-ranging wildlife, scientific evidence for determining a withdrawal, withholding, or discard time for meat, milk, eggs, or other food derived from the treated animal(s)

## How do I submit a nomination?

**Submit the nomination, including any attachments,** to Docket No. FDA-2018-N-4626, at <https://www.regulations.gov>. Or mail to: Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Be sure to include the docket number.

**Note:** If you have any questions while preparing or submitting your nominations, please contact CVM for assistance via email by clicking following link: [CVM Compounding](#)

## What happens after I submit my nomination?

**FDA adds bulk drug substances that have been nominated and are under review to the [List of Nominated Bulk Drug Substances Currently Under Review](#).**

- At this time, FDA generally intends to refrain from taking enforcement action when these bulk drug substances currently under review are used to compound a finished drug as described in the nomination.
- Bulk drug substances will remain on this list only during FDA's initial review of their nomination.
- After FDA completes its review, the bulk drug substance will be placed on one of these lists: [Bulk Drug Substances Reviewed and Not Listed](#), [List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals](#), or [List of Bulk Drug Substances for Compounding Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species](#)
- Should the bulk drug substance be placed on the list [Bulk Drug Substances Reviewed and Not Listed](#), additional or new information can be submitted at any time for FDA's review.

## Where can I find more information?

**Visit FDA's website: [Nominations for Bulk Drug Substances for Compounding: \(1\) Office Stock Drugs for Use in Nonfood-Producing Animals or \(2\) Drugs for Use in Food-Producing Animals or Free-Ranging Wildlife Species for more information](#).**

**Questions?:** If you have any questions while preparing or submitting your nominations, please contact CVM for assistance via email by clicking following link: [CVM Compounding](#)