Unapproved Drug Decision Tree*

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Is the active ingredient in an approved NDA or ANDA listed in the Orange Book?

Yes

Is the ingredient, strength, dosage form, route of administration, and directions for use, etc. being reviewed under the OTC Drug Review System?

Yes

Was the ingredient reviewed under DESI?

Yes

Was the ingredient found effective for any indication?

Yes

Was there a final determination that the ingredient is ineffective for the indication for which it is offered?

Yes

505(b)(1) or 505(b)(2) NDA required

No

ANDA required

No

Is there anything different (e.g., indication, strength, dosage form, route of administration, etc.)?

Yes

505(b)(1) or 505(b)(2) NDA required

OR

ANDA with acceptable Suitability Petition

No

Is the ingredient, strength, dosage form, route of administration, and directions for use, etc. being reviewed under the OTC Drug Review System?

No

Is the indication different?

Yes

Is the applicable monograph final?

Yes

The product can be marketed.

No

The product can be marketed if it meets monograph specifications.

No

Has the ingredient in the specific OTC drug category been placed in 21 CFR 310.545 or the drug product been affected by restrictions such as those in 21 CFR 310.502 and 21 CFR 310.503?

Yes

No

Products subject to a pending DESI NOOH may be marketed until final DESI notice is published.

* While this decision tree provides an overall approach to understanding how marketed unapproved drugs may comply with requirements under the FDCA under current policies, as applied to any particular drug product there may be variations and additional relevant factors. For instance, when a drug contains more than one active ingredient, each ingredient, as well as the combination as a whole, will need to be addressed. In addition, when an ingredient has been reviewed in more than one DESI proceeding, the Agency will apply the regulation at 21 CFR 310.6 to determine which proceeding applies to a particular drug product.