Over-the-Counter List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic

To improve transparency and encourage the development and submission of abbreviated new drug applications (ANDAs) for drugs with limited competition, FDA is publishing a list, consistent with the methodology described below, of approved and active over-the-counter (OTC) new drug application (NDA) drug products that are off-patent and off-exclusivity, and for which the FDA has not approved an ANDA referencing that NDA drug product. This list only includes OTC drug products that are approved and currently marketed under an NDA and does not include OTC drug products covered by an OTC monograph, as those products are not approved through the NDA or ANDA process. For more information about drug products covered by OTC monographs, please review the information available from FDA's website related to the OTC Drug Monograph Process.

Part I of the list identifies those OTC drug products for which FDA could immediately accept an ANDA without prior discussion.

Part II identifies OTC drug products for which ANDA development or approval may raise potential legal, regulatory, or scientific issues that should be addressed with the Agency prior to considering submission of an ANDA.

The Appendix identifies OTC NDA drug products that were removed from Part I or Part II of the list because one or more ANDAs referencing such NDA drug products have been approved since the previous list publication.

Sponsors wishing to pursue approval of ANDAs referencing drug products identified in Part II of this list generally should submit an initial inquiry to the Office of Generic Drugs at genericdrugs@fda.hhs.gov. Sponsors may be referred to the Office of New Drugs under certain circumstances, for example, if the product is not eligible for submission or approval as an ANDA but may be considered for submission under another abbreviated approval pathway. Sponsors should identify the product's established name and NDA number in any inquiry.

- For some products in Part II of the list, submission and/or approval of an ANDA via the 505(j) pathway may not be appropriate; section 505(b)(2) of the FD&C Act may be an appropriate abbreviated approval pathway for such products.
- For other products in Part II of the list, there are regulatory or scientific complexities that may be addressed with additional information exchange between FDA and a prospective ANDA sponsor (e.g., there is no applicable product-specific guidance or the product is considered complex).

We have excluded any NDA drug products that have been approved within the past year or were switched from prescription to OTC status within the last year, as it generally is too soon for an ANDA referencing such products to have been approved.

FDA intends to update the list every six months. The current methodology for creating and reviewing the list is set forth at the bottom of the list. We welcome suggestions concerning the methodology, as well as suggestions for any OTC NDA drug products that should be added to (or, in limited cases, removed from) the list. Please direct correspondence to genericdrugs@fda.hhs.gov, providing your name, e-mail address, phone number, NDA number, established name, and dosage form of any NDA drug product that should be added to or, in limited cases, removed from the list.

OTC List Part I

Ingredient	Approved NDA	Dosage Form	Strength
ACETAMINOPHEN	N018337	SUPPOSITORY	80MG
CETIRIZINE HYDROCHLORIDE	N022429	CAPSULE	5MG
CETIRIZINE HYDROCHLORIDE	N022429	CAPSULE	5MG
CETIRIZINE HYDROCHLORIDE	N021621	TABLET, CHEWABLE	2.5MG
CETIRIZINE HYDROCHLORIDE	N021621	TABLET, CHEWABLE	10MG **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons**
CHLORHEXIDINE GLUCONATE	N017768	SOLUTION	4%
CHLORPHENIRAMINE MALEATE; IBUPROFEN; PHENYLEPHRINE HYDROCHLORIDE	N022113	TABLET	4MG;200MG;10MG
CHLORPHENIRAMINE MALEATE; IBUPROFEN; PHENYLEPHRINE HYDROCHLORIDE	N022113	TABLET	4MG;200MG;10MG
CHLORPHENIRAMINE MALEATE; IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	N021587	SUSPENSION	1MG/5ML;100MG/5ML;15MG/5ML
FAMOTIDINE	N020801	TABLET, CHEWABLE	20MG
IBUPROFEN	N021472	CAPSULE	200MG
IBUPROFEN	N020589	SUSPENSION	100MG/5ML
IBUPROFEN	N020589	SUSPENSION	100MG/5ML
IBUPROFEN	N020944	TABLET, CHEWABLE	50MG
IBUPROFEN	N020944	TABLET, CHEWABLE	100MG
IBUPROFEN	N020267	TABLET	100MG
IBUPROFEN	N020602	TABLET	100MG
IBUPROFEN SODIUM	N201803	TABLET	EQ 200MG BASE
IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	N021373	SUSPENSION	100MG/5ML;15MG/5ML
IBUPROFEN; PSEUDOEPHEDRINE HYDROCHLORIDE	N019899	TABLET	200MG;30MG
KETOCONAZOLE	N020310	SHAMPOO	1%
KETOTIFEN FUMARATE	N021996	SOLUTION/DROPS	EQ 0.025% BASE
KETOTIFEN FUMARATE	N021996	SOLUTION/DROPS	EQ 0.025% BASE
LOPERAMIDE HYDROCHLORIDE	N021855	CAPSULE	1MG

OTC List Part I

Ingredient	Approved NDA	Dosage Form	Strength
LORATADINE	N021375	TABLET, ORALLY DISINTEGRATING	10MG
NAPHAZOLINE HYDROCHLORIDE; PHENIRAMINE MALEATE	N020226	SOLUTION/DROPS	0.025%;0.3%
NICOTINE	N020165	FILM, EXTENDED RELEASE	7MG/24HR
NICOTINE	N020165	FILM, EXTENDED RELEASE	14MG/24HR
NICOTINE	N020165	FILM, EXTENDED RELEASE	21MG/24HR
ORLISTAT	N021887	CAPSULE	60MG
OXYBUTYNIN	N202211	FILM, EXTENDED RELEASE	3.9MG/24HR
OXYMETAZOLINE HYDROCHLORIDE	N019407	SOLUTION/DROPS	0.03%
PURIFIED WATER	N022305	SOLUTION	98%
TERBINAFINE	N021958	GEL	1%
TERBINAFINE HYDROCHLORIDE	N021124	SOLUTION	1%

OTC List Part II

Ingredient	Approved NDA	Dosage Form	Strength
ALCOHOL; CHLORHEXIDINE GLUCONATE	N021074	SOLUTION	61%;1%
AVOBENZONE; ECAMSULE; OCTOCRYLENE	N021502	CREAM	2%;2%;10%
AVOBENZONE; ECAMSULE; OCTOCRYLENE	N021501	CREAM	2%;3%;10%
AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE	N021471	CREAM	2%;2%;10%;2%
AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE	N022009	CREAM	2%;3%;10%;5%
AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE	N022009	CREAM	2%;3%;10%;5%
BENTOQUATAM	N020532	LOTION	5%
CHLORHEXIDINE GLUCONATE	N019127	AEROSOL, METERED	4%
CHLORHEXIDINE GLUCONATE	N207964	CLOTH	2%
CHLORHEXIDINE GLUCONATE	N019258	SOLUTION	4%
CHLORHEXIDINE GLUCONATE	N020111	SOLUTION	0.75%
CHLORHEXIDINE GLUCONATE	N019258	SOLUTION	2%
CHLORHEXIDINE GLUCONATE	N019422	SOLUTION	2%
CHLORHEXIDINE GLUCONATE	N019125	SOLUTION	4%
CHLORHEXIDINE GLUCONATE	N018300	SOLUTION	0.50%
CHLORHEXIDINE GLUCONATE	N019822	SPONGE	4%
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	N020832	SPONGE	2%;70% (3ML)
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	N020832	SPONGE	2%;70% (10.5ML)
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	N020832	SPONGE	2%;70% (26ML)
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	N020832	SPONGE	2%;70% (1ML)
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	N020832	SPONGE	2%;70% (1.5ML)
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	N021555	SWAB	2%;70% (0.67ML)
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	N021555	SWAB	2%;70% (1.75ML)
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	N021555	SWAB	2%;70% (5.25ML)
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	N021524	SWAB	3.15%;70% (5.1ML)
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	N021524	SWAB	3.15%;70% (1ML)
CHLORHEXIDINE GLUCONATE; ISOPROPYL ALCOHOL	N021524	SWAB	3.15%;70% (1.6ML)
CLOTRIMAZOLE	N021143	CREAM	2%
IODINE POVACRYLEX; ISOPROPYL ALCOHOL	N021586	SPONGE	EQ 0.7% IODINE;74% (6ML)
IODINE POVACRYLEX; ISOPROPYL ALCOHOL	N021586	SPONGE	EQ 0.7% IODINE;74% (26ML)
MICONAZOLE NITRATE	N020288	CREAM, SUPPOSITORY	2%,100MG
NIZATIDINE	N020555	TABLET	75MG
POVIDONE-IODINE	N019522	SOLUTION	1%
TERBINAFINE HYDROCHLORIDE	N021124	SPRAY	1%

OTC List Appendix

Ingredient	Approved NDA	Dosage Form	Strength
FAMOTIDINE	N020902	TABLET;ORAL	10MG
LORATADINE	N021734	SUSPENSION;ORAL	1MG/ML
LORATADINE	N021891	TABLET, CHEWABLE;ORAL	10MG
PSEUDOEPHEDRINE HYDROCHLORIDE	N020021	TABLET, EXTENDED RELEASE;ORAL	240MG

Methodology[1]

1. The list is based on the Orange Book Data Files, accessed December 15, 2025.

2. The list includes Orange Book-listed drug products that are marketed as over-the-counter drug products.[2] The Agency has identified the corresponding NDA numbers for drug products included on the list to assist applicants with identification of the correct reference listed drug (RLD).

3. A given drug product is included on the list if:

   a. There is at least one active and approved NDA for the drug product,[3,4] and

   b. The relevant NDA for the drug product is marketed as an OTC drug product, and

   c. There are no approved ANDAs for the drug product,[5,6] and

   d. There are no unexpired patents or exclusivities listed in the Orange Book for the drug product.[7]

4. Each drug product and corresponding NDA number is then placed on either Part I or Part II of the list based on the following criteria:

   a. Part I of the list identifies those drug products for which FDA could immediately accept an ANDA without prior discussion with the Agency.

   b. Part II identifies drug products for which development and submission of an ANDA could involve potential legal, regulatory, or scientific issues that should be addressed with the Agency prior to considering submission of an ANDA.

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[1] The methodology used to create this list is based off the methodology used to compile the *List of Off-Patent, Off-Exclusivity Prescription Drugs without an Approved Generic*. Similar to that methodology, this list is organized based on drug products, not active ingredients. This means that an active and approved NDA for a particular active ingredient, dosage form, and strength will be included on the list if there are no approved ANDAs for that active ingredient, dosage form, and strength approved in the NDA.

[2] Products approved under NDAs that are marketed as over-the-counter drugs are listed in the Orange Book with a marketing status of "OTC" or "Over-the-counter." Drug products marketed under an OTC monograph are not listed in Orange Book and are not included on this list.

[3] "Active and approved" means that the NDA for the relevant drug product is approved and listed in the Orange Book, and is not identified as a "discontinued" product in the Orange Book. If all approved NDAs for a given drug product are identified as "discontinued" in the Orange Book, that drug product is not included on the list.

[4] Drug products with only approved and Orange Book-listed ANDAs but no Orange Book-listed NDAs are not included on the list.

[5] Drug products with an approved but discontinued ANDA are not included on the list.

[6] If a drug product is available under an OTC monograph and an OTC NDA, but there are no approved ANDAs for the drug product available under the NDA and the product otherwise meets the criteria for inclusion, the drug product will be included on the list.

[7] Drug products that have at least one Orange Book-listed patent or exclusivity are not included on the list.