Dated: October 8, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1038]

Determination That ROBAXIN and ROBAXIN–750 (Methocarbamol), Oral Tablets, 500 Milligrams and 750 Milligrams, and Other Drug Products, Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) has determined that the drug products listed in this document were not withdrawn from sale for reasons of safety or effectiveness. This determination means that FDA will not begin procedures to withdraw approval of abbreviated new drug applications (ANDAs) that refer to these drug products, and it will allow FDA to continue to approve ANDAs that refer to the products as long as they meet relevant legal and regulatory requirements.

FOR FURTHER INFORMATION CONTACT: Stacy Kane, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–8363, *Stacy.Kane@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(j)) allows the submission of an ANDA to market a generic version of a previously approved drug product. To obtain approval, the ANDA applicant must show, among other things, that the generic drug product: (1) Has the same active ingredient(s), dosage form, route of administration, strength, conditions of use, and (with certain exceptions) labeling as the listed drug, which is a version of the drug that was previously approved and (2) is bioequivalent to the listed drug. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

Section 505(j)(7) of the FD&C Act requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is generally known as the ''Orange Book.'' Under FDA regulations, a drug is removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness, or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

Under § 314.161(a) (21 CFR 314.161(a)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness: (1) Before an ANDA that refers to that listed drug may be approved, (2) whenever a listed drug is voluntarily withdrawn from sale and ANDAs that refer to the listed drug have been approved, and (3) when a person petitions for such a determination under 21 CFR 10.25(a) and 10.30. Section 314.161(d) provides that if FDA determines that a listed drug was withdrawn from sale for safety or effectiveness reasons, the Agency will initiate proceedings that could result in the withdrawal of approval of the ANDAs that refer to the listed drug.

FDA has become aware that the drug products listed in the table are no longer being marketed.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 011011	ROBAXIN; ROBAXIN–750.	Methocarbamol	500 milligrams (mg); 750 mg.	Tablet; Oral	Auxilium Pharmaceuticals LLC.
NDA 018704	LOPRESSOR	Metoprolol Tartrate	1 mg/milliliter (mL)	Injectable; Injection	Novartis.
NDA 018917	SECTRAL	Acebutolol Hydrochloride.	Equivalent to (EQ) 200 mg base; EQ 400 mg base.	Capsule; Oral	Promius Pharma, LLC.
NDA 019546	DYNACIRC	Isradipine	2.5 mg; 5 mg	Capsule; Oral	SmithKline Beecham.
NDA 019555	DIPROLENE AF	Betamethasone Dipropionate.	EQ 0.05% base	Cream, Augmented; Topical.	Merck Sharp Dohme.
NDA 019625	ELOCON	Mometasone Furoate	0.10%	Cream; Topical	Merck Sharp Dohme.
NDA 020089	ZOVIRAX	Acyclovir	400 mg; 800 mg	Tablet; Oral	Mylan.
NDA 020136	DEMADEX	Torsemide	5 mg; 10 mg; 20 mg; 100 mg.	Tablet; Oral	Mylan Specialty, L.P.
NDA 020198	ADALAT CC	Nifedipine	30 mg; 60 mg; 90 mg	Tablet, Extended Release; Oral.	Alvogen.
NDA 020539	LAMISIL	Terbinafine Hydrochloride.	EQ 250 mg base	Tablet; Oral	Novartis.
NDA 020634	LEVAQUIN	Levofloxacin	250 mg; 500 mg; 750 mg.	Tablet; Oral	Janssen Research & Development, LLC.
NDA 020716	VICOPROFEN	Hydrocodone Bitartrate; Ibuprofen.	7.5 mg; 200 mg	Tablet; Oral	Abbvie, Inc.
NDA 020738	TEVETEN	Eprosartan Mesylate	EQ 300 mg base; EQ 400 mg base; EQ 600 mg base.	Tablet; Oral	Abbvie, Inc.
NDA 021001	AXERT	Almotriptan Malate	EQ 6.25 mg base; EQ 12.5 mg base.	Tablet; Oral	Janssen Pharms.
NDA 022205	GIAZO	Balsalazide Disodium	1.1 gram	Tablets; Oral	Valeant Pharms. International.
NDA 022439	ZUTRIPRO	Chlorpheniramine Maleate, Hydrocodone Bitartrate, and Pseudoephedrine Hydrochloride.	4 mg/5 mL; 5 mg/5 mL; 60 mg/5 mL.	Solution; Oral	Persion Pharms, LLC.

Application No.	Drug name	Active ingredient(s)	Strength(s)	Dosage form/route	Applicant
NDA 022510 ...	ABSTRAL	Fentanyl Citrate	EQ 0.1 mg base; EQ 0.2 mg base; EQ 0.3 mg base; EQ 0.4 mg base; EQ 0.6 mg base; EQ 0.8 mg base.	Tablet; Sublingual	Sentynl Therapeutics, Inc.
NDA 050011 ...	PATHOCIL	Dicloxacillin Sodium	EQ 250 mg base; EQ 500 mg base.	Capsule; Oral	Wyeth-Ayerst Labs.
NDA 204308 ...	EPANED KIT	Enalapril Maleate	1 mg/mL	For Solution; Oral	Silvergate Pharms., Inc.
NDA 207233 ...	VIVLODEX	Meloxicam	5 mg; 10 mg	Capsule; Oral	Zyla.

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The Discontinued Drug Product List identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the NDAs listed are unaffected by the discontinued marketing of the products subject to those NDAs. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: October 19, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–23084 Filed 10–21–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1037]

Fresenius USA, Inc., et al.; Withdrawal of Approval of 216 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 216 abbreviated new drug applications (ANDAs) from multiple holders of those ANDAs. The basis for the withdrawal is that these ANDA holders have repeatedly failed to submit required annual reports for those ANDAs.

DATES: Approval is withdrawn as of November 22, 2021.

FOR FURTHER INFORMATION CONTACT: James Hanratty, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–4718, *James.Hanratty@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The holders of an approved application to market a new drug for human use are required to submit annual reports to FDA concerning their approved application in accordance with §§ 314.81 and 314.98 (21 CFR 314.81 and 314.98). In the **Federal Register** of January 9, 2020 (85 FR 1160), FDA published a notice offering an opportunity for a hearing (NOOH) on a proposal to withdraw approval of 249 ANDAs because the holders of those ANDAs had repeatedly failed to submit the required annual reports for those ANDAs (''Fresenius USA, Inc., et al.; Proposal To Withdraw Approval of 249 Abbreviated New Drug Applications; Opportunity for a Hearing'').[1] The holder of ANDA 085882, ANDA 086262, and ANDA 0866263 responded to the NOOH and requested a hearing. The remaining holders of those ANDAs did not respond to the NOOH. Failure to file a written notice of participation and request for hearing as required by § 314.200 constitutes an election by those holders of the ANDAs not to make use of the opportunity for a hearing concerning the proposal to withdraw approval of their ANDAs and a waiver of any contentions concerning the legal status of the drug products. Therefore, FDA is withdrawing approval of the 216 applications listed in table 1.

I. Annual Reports Submitted

In response to the NOOH, one firm requested a hearing and had previously submitted an annual report for each of its three ANDAs. Therefore, FDA rescinds its proposal to withdraw approval of the following three ANDAs:

Chartwell RX Sciences, LLC, 77 Brenner Dr., Congers, NY 10920:

- ANDA 085882, DUVOID (bethanechol chloride) Tablets, 50 milligrams (mg)
- ANDA 086262, DUVOID (bethanechol chloride) Tablets, 10 mg
- ANDA 086263, DUVOID (bethanechol chloride) Tablets, 25 mg

Another three firms notified the Agency that they had submitted an annual report for each of its ANDAs listed in the NOOH. Therefore, FDA rescinds its proposal to withdraw approval of the following eight ANDAs:

Jerome Stevens Pharmaceuticals Inc., 60 DaVinci Dr., Bohemia, NY 11716:

- ANDA 062869, CEPHALEXIN Capsules USP, EQ 500 mg base
- ANDA 062870, CEPHALEXIN Capsules USP, EQ 250 mg base
- ANDA 074988, ASPIRIN, CAFFEINE, AND ORPHENADRINE CITRATE Tablets, 385 mg/30 mg/25 mg, and 770 mg/60 mg/50 mg
- ANDA 081145, ASPIRIN AND METHOCARBAMOL Tablets, 325 mg/400 mg

MIPS Cyclotron and Radiochemistry Facility, 1201 Welch Rd., Rm. PS049, Stanford, CA 94305:

- ANDA 204472, FLUDEOXYGLUCOSE F–18 Injection USP, 20–300 millicuries (mCi)/milliliters (mL)
- ANDA 204517, SODIUM FLUORIDE F–18 Injection, 10–200 mCi/mL
- ANDA 204535, AMMONIA N–13 Injection USP, 3.75–37.5 mCi/mL

Milex Products, Inc., 5915 Northwest Hwy., Chicago, IL 60631:

- ANDA 072196, MILOPHENE (clomiphene citrate) Tablets, 50 mg

II. Previously Consolidated Application

Sandoz, Inc., 4700 Eon Dr., Wilson, NC 27893, notified the Agency that ANDA 084631, QUINIDINE SULFATE Tablets USP, 200 mg, had previously been consolidated with ANDA 088072. Therefore, FDA rescinds its proposal to withdraw approval of this ANDA.

[1] 85 FR 1160, published on January 9, 2020, incorrectly listed 249 as the number of the ANDAs FDA proposed to withdrawal. 85 FR 1160 listed 248 ANDAs in the table included in the notice.