November 5, 2020

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

The undersigned Petitioner submits this Citizen Petition pursuant to the Federal Food, Drug and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. §§ 10.25(a) and 10.30 and pursuant to Sections 505(j) and 505(w) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and 21 C.F.R. §§ 314.122 and 314.161 to request that the Food and Drug Administration ("FDA") determine whether a listed drug was withdrawn for safety or effectiveness reasons.

I. ACTION REQUESTED

Petitioner requests that FDA determine whether Atrovent (ipratropium bromide) Nasal Spray, 0.021MG/SPRAY approved under New Drug Application ("NDA") Number N020393 and Atrovent (ipratropium bromide) Nasal Spray, 0.042MG/SPRAY approved under New Drug Application ("NDA") Number N020394, held by BOEHRINGER INGELHEIM PHARMACEUTICALS INC, has been voluntarily withdrawn for reasons of safety or effectiveness.

II. STATEMENT OF GROUNDS

Under the FDC Act, an ANDA must rely on FDA's approval findings for a Reference Listed Drug ("RLD"). See FDC Act § 505(j)(2). If a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an Abbreviated NDA ("ANDA") for the drug must Petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness. See 21 C.F.R. §§ 314.122 and 314.161. If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from the Orange Book. See id.§ 314.162. If FDA determines that the listed drug was not withdrawn from

sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as an RLD.

The Orange Book currently identifies Atrovent Nasal Spray, 0.021MG/SPRAY approved on Oct 20, 1995 under NDA Number N020393 and Atrovent Nasal Spray, 0.042MG/SPRAY approved on Oct 20, 1995 under NDA Number N020394, in the "Discontinued Drug Product List" section of the Orange Book.

In 2018, FDA published a notice in the Federal Register that approval of NDA Numbers N020393 and N020394 for Atrovent Nasal Spray were being withdrawn pursuant to the applicant's request that the drug products were no longer marketed and that the approval of the applications be withdrawn. See 83 Fed. Reg. 32,305 (July 12, 2018), as reproduced below:

collections of information in 21 CFR part 58 have been approved under OMB control number 0910–0119; the collections of information in 21 CFR part 312 have been approved under OMB control number 0910–0014; the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338; the collections of information in the guidance entitled "Expedited Programs for Serious Conditions—Drugs and Biologics" have been approved under OMB control number 0910–0765; and the collections of information in the guidance entitled "Formal Meetings Between the FDA and Sponsors or Applicants" have been approved under OMB control number 0910–0429.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov*.

Dated: July 5, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–14871 Filed 7–11–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–2180]

Concordia Pharmaceuticals, Inc., et al.; Withdrawal of Approval of 29 New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of 29 new drug applications (NDAs) from multiple applicants. The holders of the applications notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

DATES: Approval is withdrawn as of August 13, 2018.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6248, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

Application No.	Drug	Applicant
NDA 011287	Kayexalate (sodium polystyrene sulfonate) Powder for Suspension, 453.6 gram (g)/bottle.	Concordia Pharmaceuticals, Inc., c/o Mapi USA, Inc., 2343 Alexandria Dr., Lexington, KY 40504.
NDA 012249	Librium (chlordiazepoxide hydrochloride (HCl)) Capsules, 5 milligram (mg), 10 mg, and 25 mg.	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 016211	Miochol (acetylcholine chloride) for Ophthalmic Solution, 20 mg/vial	Novartis Pharmaceuticals Corp., One Health Pl., East Hanover, NJ 07936.
NDA 018674	Metro I.V. (metronidazole) Injection, 500 mg/100 milliliter (mL)	B. Braun Medical, Inc., 901 Marcon Blvd., Allentown, PA 18109.
NDA 018852	Sulfamethoxazole and Trimethoprim Tablets USP, 400 mg; 80 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
NDA 018854	Sulfamethoxazole and Trimethoprim Tablets USP, 800 mg; 160 mg	Do.
NDA 018988	Vasocidin (prednisolone sodium phosphate and sulfacetamide sodium) Ophthalmic Solution, equivalent to (EQ) 0.23% phosphate/10%.	Novartis Pharmaceuticals Corp.
NDA 019844	Isolyte H in Dextrose 5% in Plastic Container Injection	B. Braun Medical, Inc.
NDA 019870	Isolyte M in Dextrose 5% in Plastic Container Injection	Do.
NDA 019964	Terazol 3 (terconazole) Vaginal Cream, 0.8%	Janssen Pharmaceuticals, Inc., 1125 Trenton-Harbourton Rd., Titusville, NJ 08560.
NDA 020000	Dextrose 5% in Ringer's in Plastic Container Injection	B. Braun Medical, Inc.
NDA 020393	Atrovent (ipratropium bromide) Nasal Spray, 0.021 mg/spray	Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877–0368.
NDA 020394	Atrovent (ipratropium bromide) Nasal Spray, 0.042 mg/spray	Do.
NDA 021180	Ortho Evra (ethinyl estradiol; norelgestromin) Transdermal Patch, 0.035 mg/24 h; 0.15 mg/24 h.	Janssen Pharmaceuticals, Inc., 1000 U.S. Route 202, P.O. Box 300, Raritan, NJ 08869–0602.

Petitioner is not aware of any information indicating that the withdrawal was made for safety or effectiveness reasons. Petitioner is further unaware of any reason why Atrovent Nasal Spray, approved under NDA Numbers N020393 and N020394 may have been removed from sale while

other ANDA holders for generic Atrovent Nasal Spray are still in the market and thus believes that the discontinuation of Atrovent Nasal Spray, approved under NDA Numbers N020393 and N020394, was due only to commercial considerations. Petitioner requests that FDA determine that Atrovent Nasal Spray RLDs, approved under NDA Numbers N020393 and N020394, were not withdrawn for reasons of safety or effectiveness.

III. ENVIRONMENTAL IMPACT

An environmental assessment report on the action requested in this petition is not required under 21 C.F.R. § 25.31.

IV. ECONOMIC IMPACT

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. Petitioner hereby commits to promptly provide this information, if so requested.

V. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned. This petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which is unfavorable to the petition.

Sincerely,

Michelle R. Ryder

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