

submitted by Nexgen (Nexgen Objection at 78–82). According to Nexgen, its pending citizen petition requests that FDA find that the prescription MiraLAX NDA was not withdrawn for reasons of safety and efficacy and to declare Nexgen's prescription ANDA as the new RLD drug for prescription PEG 3350 products (Objection at 79). It is not necessary to finalize the TFM for OTC laxatives or to respond to Nexgen's pending citizen petition prior to the withdrawal of the ANDAs. As discussed elsewhere in this order, the OTC MiraLAX labeling is consistent with the TFM for OTC laxatives with respect to the use of the phrase "relieves" versus "treats" and the instruction to "use no more than 7 days" and "Stop use and ask a doctor if . . . you need to use a laxative for longer than 1 week." However, this labeling does not change the factors relevant to determining whether there is a meaningful difference between the prescription and nonprescription PEG 3350 products. If an order is entered withdrawing the approval of the ANDAs, the issues raised in the citizen petition will be moot.

Nexgen complains that FDA largely based its draft proposed order on a January 2013 letter from Merck rather than more carefully reviewing and responding to each argument raised by the ANDA holders, rendering the order suspect (Nexgen Objection at 75–76). In fact, both the Merck letter and the draft proposed order were written in response to the issues and evidence submitted by the ANDA holders. The draft proposed order provided a lengthy analysis addressing the arguments and evidence submitted by the ANDA holders. The fact that the draft proposed order ultimately reached the same conclusion urged by the NDA holder (and the result proposed by CDER in the NOOH) does not render that order "suspect."

In sum, the Commissioner believes that the change in prescription to nonprescription status was a complete switch. In addition, the Commissioner concludes that there is not a meaningful difference between the prescription and nonprescription products approved by FDA based on the arguments discussed in this section. The Commissioner finds that the ANDA holders have failed to raise a genuine and substantial issue of fact regarding a meaningful difference between prescription and nonprescription MiraLAX that requires

a hearing. The Commissioner does not find the arguments advanced by the PEG 3350 ANDA holders on the topics discussed in this section persuasive and is entering summary judgment against them.

IV. Findings and Order

Based upon the above, the Commissioner finds that the PEG 3350 ANDA holders have failed to raise a genuine and substantial issue of fact requiring a hearing in their responses to the NOOH. A hearing, therefore, is not required under § 12.24(b). The PEG 3350 ANDA holders did not submit any specifically identified reliable evidence demonstrating that a hearing is necessary. Other evidence submitted was not material to the issues in this proceeding. Even if the Commissioner were to accept these factual assertions as having some weight, such evidence does not present a sufficient area of disagreement to require an evidentiary hearing. Rather, the evidence is "so one-sided that [FDA] must prevail as a matter of law." (See *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986).)

In addition to finding that the ANDA holders have failed to raise a genuine and substantial issue of fact that requires a hearing, the Commissioner does not find the arguments advanced by the PEG 3350 ANDA holders persuasive and is entering summary judgment against them under § 314.200(g). There is no meaningful difference between the ANDA holders' PEG 3350 products and OTC MiraLAX. The labeling of the ANDA holders' PEG 3350 products is false and misleading because it bears the "Rx only" symbol when FDA has determined in approving OTC MiraLAX that the drug can be used safely and effectively in the nonprescription setting and does not meet the criteria for a prescription drug in 503(b)(1) of the FD&C Act. This false and misleading labeling was not corrected within a reasonable time after receipt of written notice from FDA. Therefore, under section 505(e) of the FD&C Act and under authority delegated to the Commissioner, the PEG 3350 ANDA holders' requests for a hearing are denied.

It is ordered, that pursuant to section 505(e) of the FD&C Act (21 U.S.C. 355(e)), that approval of the following ANDAs: ANDA 76–652 held by Kremers Urban Pharmaceuticals, Inc.; ANDA 77–736 held by Breckenridge

Pharmaceutical, Inc.; ANDA 77–706 held by Nexgen Pharma, Inc. (formerly known as Anabolic Laboratories, Inc.); ANDA 77–893 held by Paddock Laboratories, LLC.; and ANDA 77–445 held by Teva Pharmaceutical, USA; and all amendments and supplements to them, be and hereby are withdrawn, effective May 2, 2018.

Dated: March 22, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–1141]

Mallinckrodt Inc. et al.; Withdrawal of Approval of Five New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of five 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 May 2, 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 006383	Methadone Hydrochloride (HCl) Powder, 50 grams (g)/bottle, 100 g/bottle, and 500 g/bottle.	Mallinckrodt Inc., 675 McDonnell Blvd., Hazelwood, MO 63042.

Application No.	Drug	Applicant
NDA 020716	Vicoprofen (hydrocodone bitartrate and ibuprofen) Tablets, 7.5 milligrams (mg)/200 mg.	AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.
NDA 021692	Ultram ER (tramadol HCl) Extended-Release Tablets, 100 mg, 200 mg, and 300 mg.	Valeant Pharmaceuticals North America LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
NDA 207621	Troxyca ER (oxycodone HCl and naltrexone HCl) Extended-Release Capsules, 10 mg/1.2 mg, 20 mg/2.4 mg, 30 mg/3.6 mg, 40 mg/4.8 mg, 60 mg/7.2 mg, and 80 mg/9.6 mg.	Pfizer Inc., 235 East 42nd St., New York, NY 10017.
NDA 207975	Vantrela ER (hydrocodone bitartrate) Extended-Release Tablets, 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg.	Teva Branded Pharmaceutical Products R&D, Inc., 41 Moores Rd., P.O. Box 4011, Frazer, PA 19355.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of May 2, 2018. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on May 2, 2018 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: March 21, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Advisory Committee on Rural Health and Human Services

AGENCY: Health Resources and Service Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, notice is hereby given that a meeting is scheduled for the National Advisory Committee on Rural Health and Human Services (NACRHHS). This meeting will be open to the public. Information about the NACRHHS and the agenda for this meeting can be obtained by accessing the NACRHHS website at <http://www.hrsa.gov/advisorycommittees/rural/>.

DATES: The meeting will be held on April 16, 2018, from 8:45 a.m.–5:00 p.m. EDT, April 17, 2018, from 8:30 a.m.–5:15 p.m. EDT, and April 18, 2018, from 8:30 a.m.–11:00 a.m. EDT.

ADDRESSES: This meeting will be held at The Saratoga Hilton. The address for the meeting is 534 Broadway Saratoga Springs, NY 12866-2209, (855) 605-0316.

FOR FURTHER INFORMATION CONTACT:

Steve Hirsch, MSLS, Administrative Coordinator, NACRHHS, HRSA, 17W29-C, 5600 Fishers Lane, Rockville, MD 20857, Telephone (301) 443-0835, Fax (301) 443-2803.

SUPPLEMENTARY INFORMATION:

NACRHHS provides counsel and recommendations to the Secretary with respect to the delivery, research, development, and administration of health and human services in rural areas. During the meeting the Committee will examine the issues of Assessing and Mitigating the Effect of Adverse Childhood Experiences and Health Insurance Markets in Rural Areas; conduct site visits to the Adirondack Health Institute in Glens Falls, New York and St. Vincent de Paul Catholic Church in Cobleskill, New York, to visit the Head Start Program; and summarize key findings and develop a work plan for the next quarter. Members of the public will also have the opportunity to provide comments.

Amy P. McNulty,

Acting Director, Division of the Executive Secretariat.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the National Vaccine Advisory Committee

AGENCY: National Vaccine Program Office, Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the Department of Health and Human

Services is hereby giving notice that a meeting is scheduled to be held of the National Vaccine Advisory Committee (NVAC). The meeting will be open to the public via teleconference; a public comment session will be held during the meeting.

DATES: The meeting will be held on May 3, 2018, from 10:30 a.m. to 12:30 p.m. ET. The confirmed meeting times and agenda will be posted on the NVAC website at <http://www.hhs.gov/nvpo/nvac/meetings/index.html> as soon as they become available.

ADDRESSES: Instructions regarding attending this meeting will be posted one week prior to the meeting at: <http://www.hhs.gov/nvpo/nvac/meetings/index.html>. Pre-registration is required for members of the public who wish to attend the meeting and who wish to participate in the public comment session. Individuals who wish to attend the meeting and/or participate in the public comment session should register at <http://www.hhs.gov/nvpo/nvac/meetings/index.html>.

FOR FURTHER INFORMATION CONTACT:

National Vaccine Program Office, U.S. Department of Health and Human Services, Room 715H, Hubert H. Humphrey Building, 200 Independence Avenue SW, Washington, DC 20201. Phone: (202) 690-5566; email: nvac@hhs.gov.

SUPPLEMENTARY INFORMATION: Pursuant to Section 2101 of the Public Health Service Act (42 U.S.C. 300aa-1), the Secretary of Health and Human Services was mandated to establish the National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines. The NVAC was established to provide advice and make recommendations to the Director of the National Vaccine Program on matters related to the Program's responsibilities. The Assistant Secretary for Health serves as Director of the National Vaccine Program. The public meeting will be dedicated to the deliberation of the draft recommendations written by