little research on ASD in adolescence and adulthood.

While there is research showing that the majority of ASD diagnoses made in early childhood are retained in adolescence with mostly stable in symptom severity, there are major gaps in our understanding of the health, functioning, and experiences of adolescents with ASD and other developmental disabilities. Many of these topics are especially relevant to public health: Adolescents and adults with ASD have been shown to have frequent health problems, high healthcare utilization and specialized service needs, high caregiving burden, require substantial supports to perform daily activities, are likely to be bullied, or isolated from society, and are likely to have food allergies or put on restrictive diets of questionable benefit. Many of these problems emerge after early childhood, and more studies are needed to estimate the frequency, severity, and predictive factors for these important outcomes in diverse cohorts of individuals with autism and other developmental conditions.

SEED Teen is a follow-up study of children who participated in the first phase of the SEED case-control study (SEED 1) in 2007–2011 when they were 2 to 5 years of age. SEED includes one of the largest cohorts of children assembled with ASD. Children will be identified from four SEED sites in Georgia, Maryland, North Carolina, and Pennsylvania. Three groups of children will be included: Children with ASD, children with other developmental (non-ASD) conditions (DD comparison group), and children from the general population who were initially sampled from birth records (POP comparison group).

The children and parents previously enrolled in SEED 1 represent a unique opportunity to better understand the long term trajectory of children identified as having ASD at early ages. Mothers or other primary caregivers who participated in SEED 1 will be re-contacted when their child is 13–17 years of age and asked to complete two self-administered questionnaires (SEED Teen Health and Development Survey and the Social Responsiveness Scale) about their child's health, development, education, and current functioning. Information from this study will allow researchers to assess the long term health and functioning of children with ASD and other developmental disabilities, family impacts associated with ASD and other DDs, and service needs and use associated with having and ASD and other DDs, particularly during the teen years.

We estimate that 1,410 SEED families are potentially eligible to participate in SEED Teen. Reading the letter and other materials in the invitation mailing will take approximately five minutes. We estimate that a minimum of 60% of parents/caregivers will be sent the invitation mailing or will be successfully contacted and participate in the invitation call (approximately 15 minutes). We estimate that 80% of the families who participate in the invitation call will meet the eligibility criteria for SEED Teen and 70% of those will enroll in SEED Teen. We assume all enrolled families will complete the follow-up call to confirm data collection packet receipt (approximately 10 minutes) and will review the materials in the data collection packet. Finally, we estimate that 90% of enrolled parents/caregivers will complete two self-administered questionnaires (SEED Teen Health and Development Survey and the Social Responsiveness Scale) and two supplemental consent forms. The two questionnaires will take approximately 60 minutes to complete, plus an additional 5 minutes to read and sign the informed consent. Therefore, we estimate the total burden hours are 303.

There are no costs to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Eligible families who were enrolled in SEED 1	Invitation Packet	470	1	5/60
Eligible families who were enrolled in SEED 1	Invitation Call Script	282	1	15/60
Families who agreed to participate in SEED Teen.	Follow-up Call	158	1	10/60
Families who agreed to participate in SEED Teen.	Data Collection Packet	158	1	5/60
Families who agreed to participate in SEED Teen.	SEED Teen Health and Development Survey	142	1	40/60
Families who agreed to participate in SEED Teen.	Social Responsive-ness Scale	142	1	20/60
Families who agreed to participate in SEED Teen.	Supplemental Consent forms	142	1	5/60

Leroy A. Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2017–20067 Filed 9–20–17; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5526]

Department of Health and Human Services, Supply Service Center et al.; Withdrawal of Approval of 27 Abbreviated New Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of 27 abbreviated new drug applications (ANDAs) 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: *Applied Date:* October 23, 2017.

FOR FURTHER INFORMATION CONTACT: Trang Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 1671, Silver Spring, MD 20993–0002, 240–402–7945.

SUPPLEMENTARY INFORMATION: The holders of the applications listed in table 1 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 abbreviated application under § 314.150(c) is without prejudice to refiling.

TABLE 1

Application No.	Drug	Applicant
ANDA 061071	Tetracycline Hydrochloride (HCl) Tablets, 250 milligrams (mg).	Department of Health and Human Services, Supply Service Center, PSC Bldg. 14 Boiler House Rd., Perry Point, MD 21902.
ANDA 062279	Grifulvin V (griseofulvin microsize) Tablets USP,125 mg, 250 mg, and 500 mg.	Valeant Pharmaceuticals North America, LLC, 400 Somerset Corporate Blvd., Bridgewater, NJ 08807.
ANDA 062398	Cephalexin Capsules, 250 mg and 500 mg	Department of Health and Human Services, Supply Service Center, PSC Bldg. 14 Boiler House Rd., Perry Point, MD 21902.
ANDA 062756	Primaxin (cilastatin sodium and imipenem) for Injection, Equivalent to (EQ) 250 mg base/vial; 250 mg/vial and EQ 500 mg base/vial; 500 mg/vial.	Merck Sharp & Dohme Corp., Subsidiary of Merck & Co., Inc., 1 Merck Dr., P.O. Box 100, Whitehouse Station, NJ 08889.
ANDA 062814	Gentamicin Sulfate in 0.9% Sodium Chloride Injection, EQ 0.8 mg base/milliliter (mL), EQ 1.2 mg base/mL, EQ 1.4 mg base/mL, EQ 1.6 mg base/mL, EQ 1.8 mg base/mL, EQ 2 mg base/mL, EQ 2.4 mg base/mL, EQ 40 mg base/100 mL, EQ 60 mg base/100 mL, EQ 70 mg base/100 mL, EQ 80 mg base/100 mL, EQ 90 mg base/100 mL, EQ 100 mg base/100 mL, and EQ 120 mg base/100 mL.	B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109.
ANDA 063239	Rocephin (ceftriaxone sodium) for Injection USP, EQ 250 mg base/vial, EQ 500 mg base/vial, and EQ 1 gram (g) base/vial.	Hoffmann-La Roche, Inc., c/o Genentech Inc., 1 DNA Way, MS 241B, South San Francisco, CA 94080.
ANDA 064127	Erythromycin Topical Solution, 2%	Renaissance Pharma, Inc., 411 South State St., Suite E–100, Newton, PA 18940.
ANDA 064146	Amikacin Sulfate in Sodium Chloride 0.9% Injection, EQ 500 mg base/100 mL.	Hospira, Inc., Subsidiary of Pfizer Inc., 375 N. Field Dr., Lake Forest, IL 60045.
ANDA 070598	Metoclopramide HCl Tablets, EQ 10 mg base	Merck Sharp & Dohme Corp., Subsidiary of Merck & Co., Inc.
ANDA 072080	Furosemide Injection USP, 10 mg/mL	Hospira, Inc., Subsidiary of Pfizer Inc.
ANDA 074601	Dipyridamole Injection, 5 mg/mL	Do.
ANDA 074720	Acyclovir Sodium Injection, EQ 25 mg base/mL	Do.
ANDA 076564	Adenosine Injection USP, 3 mg/mL	Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 078211	Quinapril HCl and Hydrochlorothiazide Tablets, EQ 10 mg base/12.5 mg, EQ 20 mg base/12.5 mg, and EQ 20 mg base/25 mg.	Sun Pharmaceutical Industries Ltd., c/o Sun Pharmaceutical Industries, Inc., 2 Independence Way, Princeton, NJ 08540.
ANDA 078935	Tramadol HCl Tablets USP, 50 mg	Northstar Healthcare Holdings, c/o Quality Regulatory Consultants, 1966 Anglers Cove, Vero Beach, FL 32963.
ANDA 080810	Halothane USP, 99.99%	Halocarbon Products Corp., 1100 Dittman Ct., North Augusta, SC 29841.
ANDA 085458	Dexamethasone Tablets USP, 0.5 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 085883	Acetaminophen and Codeine Phosphate Oral Suspension USP, 120 mg/5 mL and 12 mg/5 mL.	Actavis Mid Atlantic LLC, Subsidiary of Teva Pharmaceuticals USA, Inc., 425 Privet Rd., Horsham, PA 19044.
ANDA 085884	Cortisone Acetate Tablets USP, 25 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 086179	Carisoprodol Tablets USP, 350 mg	Do.
ANDA 086440	Atropine Sulfate and Diphenoxylate HCl Capsules, 0.025 mg/2.5 mg.	Catalent Pharma Solutions, Inc., 2725 Scherer Dr. North, St. Petersburg, FL 33716.
ANDA 087535	Methylprednisolone Sodium Succinate for Injection USP, EQ 500 mg base/vial and EQ 1 g base/vial.	Organon USA, Inc., Subsidiary of Merck and Co., Inc., 126 E. Lincoln Ave., P.O. Box 2000, Rahway, NJ 07065.
ANDA 087711	Dexamethasone Acetate Injectable Suspension USP, EQ 16 mg base/mL.	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.
ANDA 088346	Heparin Lock Flush Solution USP and 0.9% Sodium Chloride Injection USP, 10 USP heparin units/mL and 100 USP heparin units/mL.	Hospira, Inc.
ANDA 088852	Chlorpropamide Tablets USP, 100 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.

TABLE 1—Continued

Application No.	Drug	Applicant
ANDA 091201	Meropenem for Injection USP, 500 mg/vial and 1 g/vial	Sandoz Inc., 100 College Rd. West, Princeton, NJ 08540.
ANDA 200156	Armodafinil Tablets, 100 mg and 200 mg	Watson Laboratories, Inc., Subsidiary of Teva Pharmaceuticals USA, Inc.

Therefore, approval of the applications listed in table 1, and all amendments and supplements thereto, is hereby withdrawn, effective October 23, 2017. 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 table 1 that are in inventory on the date that this notice becomes effective (see the **DATES** section) 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: September 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–20107 Filed 9–20–17; 8:45 a.m.]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–5255]

Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) announces a forthcoming public advisory committee meeting of the Dermatologic and Ophthalmic Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The public meeting will be held on October 13, 2017, from 8:30 a.m. to 4 p.m.

ADDRESSES: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2017–N–5255. The docket will close on October 12, 2017. Submit either electronic or written comments on this public meeting by October 12, 2017. Late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 12, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of October 12, 2017. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before September 28, 2017, will be provided to the committee. Comments received after that date will be taken into consideration by the Agency.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2017–N–5255 for ''Dermatologic and Ophthalmic Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information