through written comments that can be submitted to the public docket (see **ADDRESSES**). When submitting comments to the docket, please provide some context to your comment by indicating whether you are an adolescent or young adult, or older adult. If you are commenting on behalf of a child or other loved one who has sickle cell disease, please indicate that and answer the following questions as much as possible from the patient's perspective.

Topic 1: The Effects of Sickle Cell Disease That Matter Most to You

1. Of all of the ways that sickle cell disease affects your health, which one to three effects have the greatest impact on your life? (Examples may include pain crises, breathing problems, difficulty concentrating, tiredness, infections, and others.)

2. How does sickle cell disease affect your life on an ''average'' day?

a. Are there activities that you cannot do at all or as well as you would like on these ''average'' days? Please describe, using specific examples. (Examples may include sleeping through the night, concentrating at work or at school, participating in physical activities, and others.)

3. How does sickle cell disease affect your life on the ''worst'' days, such as days when you have a pain crisis or have to be hospitalized for some reason?

a. Are there activities that you cannot do at all or as well as you would like on these ''worst'' days? Please describe, using specific examples.

4. What worries you most about how sickle cell disease could affect your health in the future?

5. What specific concerns do you have about sickle cell disease:

a. In infants and young children?

b. In adolescents and young adults?

c. In older adults?

Topic 2: Perspectives on Treatments for Sickle Cell Disease

1. Are you currently using any prescription medicines or medical treatments to prevent or treat any negative effects of your sickle cell disease? Please describe these treatments, which may include blood transfusions, supplemental oxygen and prescription medications such as hydroxyurea, antibiotics, pain medications, and others.

a. How well do these treatments work for you? For example, how well do they reduce your number of pain crises, hospitalizations, or strokes? How well do they help you manage your pain, breathing difficulties, or other health effects?

b. What are the biggest problems with these treatments? (Examples may include side effects of medicine, going to the hospital for treatment, frequent blood tests, etc.) How do these problems affect your daily life?

2. Besides prescription medications, what else do you do to prevent or treat any negative effects of your sickle cell disease? Please describe any medications purchased at a store without a prescription, home remedies, diet changes, massages, or other therapies.

a. What specific parts of your sickle cell disease do these treatments address?

b. How well do these treatments work for you?

c. What are the biggest problems with these treatments?

3. What parts of your sickle cell disease do your current treatments not treat at all or not as well as you would like?

4. Assuming that there is no cure for sickle cell disease, what specific things would you look for in an ideal treatment?

5. If you had the opportunity to consider participating in a clinical trial studying experimental treatments for sickle cell disease, what things would you consider when deciding whether or not to participate? Examples may include how severe your sickle cell disease is, how well current treatments are working for you, your concern about serious risks, and other things.

B. Meeting Attendance and/or Participation

If you wish to attend this meeting, visit *https://patientfocusedsickle cell.eventbrite.com.* Please register by January 27, 2014. Those who are unable to attend the meeting in person can register to participate in a live Webcast of the meeting. You will be asked to indicate in your registration whether you plan to attend in person or via the Webcast. Your registration should also contain your complete contact information, including name, title, affiliation, address, email address, and phone number.

Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of disability, please contact Graham Thompson (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. They will also be asked to send a brief summary of responses to the topic questions to *PatientFocused@fda.hhs.gov.* Panelists will be notified of their selection soon after the close of registration on January 27, 2014. FDA will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

Interested members of the public, including those who attend the meeting in person or through the Webcast, are invited to provide electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see **ADDRESSES**). Comments may be submitted until April 8, 2014.

Dated: October 31, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–26548 Filed 11–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1285]

Smith Miller and Patch Inc. et al.; Proposal to Withdraw Approval of 14 New Drug Applications; Opportunity for a Hearing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity to request a hearing on the Agency's proposal to withdraw approval of 14 new drug applications (NDAs) from multiple sponsors. The basis for the proposal is that the sponsors have repeatedly failed to file required annual reports for these applications.

DATES: Submit written requests for a hearing by December 6, 2013; submit data and information in support of the hearing request by January 6, 2014.

ADDRESSES: Identify your requests for a hearing, supporting data, and other comments with Docket No. FDA–2013–N–1285, and submit this information to the Division of Dockets Management (HFA–305), Food and Drug

Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Florine P. Purdie, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6366, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: The holders of approved applications to market new drugs for human use are required to submit annual reports to FDA concerning each of their approved applications in accordance with § 314.81 (21 CFR 314.81). The holders of the approved applications listed in table 1 have failed to submit the required annual reports and have not responded to the Agency's request by certified mail for submission of the reports.

TABLE 1—APPROVED NDAS FOR WHICH REQUIRED REPORTS HAVE NOT BEEN MADE

Application No.	Drug	Applicant
NDA 004979	Multi-Vitamin Tablets	Smith Miller and Patch Inc., P.O. Box 367, San German, PR 00753.
NDA 008176	Methostan (methandriol) Tablets	Do.
NDA 008326	Methischol (inositol/vitamin B12/racemethionine/choline chloride) Injection.	USV Pharmaceutical Corp., 500 Virginia Dr., Fort Washington, PA 19034–2779.
NDA 008362	Corticotropin Injection	Vitarine Pharmaceuticals Inc., 227–15 North Conduit Ave., Springfield Gardens, NY 11413.
NDA 009346	ACTH (corticotropin) Injection	Parke-Davis, 201 Tabor Rd., Morris Plains, NJ 07950.
NDA 009515	Hyrye (riboflavin 5'-phosphate sodium) Injection	S.F. Durst and Co., Inc., 5317–21 North Third St., Philadelphia, PA 19120.
NDA 010415	Flamotide (riboflavin 5'-phosphate sodium) Injection	Philadelphia Ampoule Laboratories, 400 Green St., Philadelphia, PA 19123.
NDA 010565	Duracton (corticotropin) Injection	Nordic Biochemicals Inc., 45 Bay State Rd., Boston, MA 02215.
NDA 010791	Rubivite (cyanocobalamin) Injection	Bel Mar Laboratories, Inc., 6–10 Nassau Ave., Inwood, NY 11696.
NDA 010831	Corticotropin Injection	Organics/LaGrange, Inc., 1935 Techny Rd., Suite 14, Northbrook, IL 60062.
NDA 011015	RU–B–12–1000 (cyanocobalamin) Injection	Dow Pharmaceutical Corp., 9550 North Zionsville Rd., Indianapolis, IN 46268.
NDA 011578	Efacin (niacin) Tablet	Person and Covey, Inc., 616 Allen Ave., Glendale, CA 91201.
NDA 017861	Acthar Gel Synthetic (seractide acetate) Injection	Armour Pharmaceutical Co., P.O. Box 511, Kankakee, IL 60901.
NDA 018087	Thyrel TRH (protirelin) Injection	Ferring Pharmaceuticals, Inc., 400 Rella Blvd., Suite 300, Suffern, NY 10901.

Therefore, notice is given to the holders of the approved applications listed in table 1 and to all other interested persons that the Director of the Center for Drug Evaluation and Research proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(e)) withdrawing approval of the applications and all amendments and supplements thereto on the ground that the applicants have failed to submit reports required under § 314.81.

In accordance with section 505 of the FD&C Act and part 314 (21 CFR part 314), the applicants are hereby provided an opportunity for a hearing to show why the applications listed previously should not be withdrawn and an opportunity to raise, for administrative determination, all issues relating to the legal status of the drug products covered by these applications.

An applicant who decides to seek a hearing must file the following: (1) A written notice of participation and request for a hearing (see **DATES**) and (2) the data, information, and analyses relied on to demonstrate that there is a genuine and substantial issue of fact that requires a hearing (see **DATES**). Any other interested person may also submit comments on this notice. The procedures and requirements governing this notice of opportunity for a hearing, notice of participation and request for a hearing, information and analyses to justify a hearing, other comments, and a grant or denial of a hearing are contained in § 314.200 and in 21 CFR part 12.

The failure of an applicant to file a timely written notice of participation and request for a hearing, as required by § 314.200, constitutes an election by that applicant not to avail itself of the opportunity for a hearing concerning the proposal to withdraw approval of the applications and constitutes a waiver of any contentions concerning the legal status of the drug products. FDA will then withdraw approval of the applications and the drug products may not thereafter lawfully be marketed, and FDA will begin appropriate regulatory action to remove the products from the market. Any new drug product marketed without an approved new drug application is subject to regulatory action at any time.

A request for a hearing may not rest upon mere allegations or denials, but must present specific facts showing that there is a genuine and substantial issue of fact that requires a hearing. Reports submitted to remedy the deficiencies must be complete in all respects in accordance with § 314.81. If the submission is not complete or if a request for a hearing is not made in the required format or with the required reports, the Commissioner of Food and Drugs will enter summary judgment against the person who requests the hearing, making findings and conclusions, and denying a hearing.

All submissions under this notice of opportunity for a hearing must be filed in four copies. Except for data and information prohibited from public disclosure under 21 U.S.C. 331(j) or 18 U.S.C. 1905, the submissions may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (section 505 (21 U.S.C. 355)) and under authority delegated to the Director,

Center for Drug Evaluation and Research, by the Commissioner of Food and Drugs.

Dated: October 30, 2013.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 2013–26491 Filed 11–5–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Customer and Other Partners Satisfaction Surveys

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for the opportunity for public comment on the proposed data collection projects, the National Institutes of Health Clinical Center (CC) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Whether the proposed collection minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and for Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. David K. Henderson, Deputy Director for Clinical Care, National Institutes of Health Clinical Center, 10 Center Drive, Bldg. 10, Rm. 6–1480, Bethesda, MD 20892 or call non-toll-free number (301) 496–3515 or email your request, including your address to: *dkh@nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: Title: Generic Clearance for Surveys of Customers and Other Partners, 0925–0458, Expiration Date 12/31/2013, Type of Submission: Extension, National Institutes of Health Clinical Center (CC), National Institutes of Health (NIH).

Need and Use of Information Collection: The information collected in these surveys will be used by Clinical Center personnel: (1) To evaluate the perceptions of various Clinical Center customers and other partners of Clinical Center services; (2) to assist with the design of modifications of these services, based on customer input; (3) to develop new services, based on customer need; (4) to evaluate the perceptions of various Clinical Center customers and other partners of implemented service modifications, and (5) for hospital accreditation. These surveys are voluntary and necessary for the proper performance of Clinical Center functions and will almost certainly lead to quality improvement activities that will enhance and/or streamline the Clinical Center's operations. The major mechanisms by which the Clinical Center will request customer input is through surveys and focus groups. The surveys will be tailored specifically to each class of customer and to that class of customer's needs. Surveys will either be collected as written documents, as faxed documents, mailed electronically or collected via the web or by telephone from customers. Information gathered from these surveys of Clinical Center customers and other partners will be presented to, and used directly by, Clinical Center management to enhance the services and operations of our organization.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 4,900.

FY 2014

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual hour burden
Clinical Center Patients	5000	1	30/60	2500
Family Members of Patients	2000	1	30/60	1000
Visitors to the Clinical Center	500	1	10/60	84
NIH Intramural Collaborators	2000	1	10/60	334
Vendors and Collaborating Commercial Enterprises	500	1	20/60	167
Professionals and Organizations Referring Patients	2000	1	20/60	667
Regulators	30	1	20/60	10
Volunteers	275	1	30/60	138

FY 2015

Type of respondent	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual hour burden
Clinical Center Patients	5000	1	30/60	2500
Family Members of Patients	2000	1	30/60	1000
Visitors to the Clinical Center	500	1	10/60	84
NIH Intramural Collaborators	2000	1	10/60	334
Vendors and Collaborating Commercial Enterprises	500	1	20/60	167
Professionals and Organizations Referring Patients	2000	1	20/60	667
Regulators	30	1	20/60	10