East, Adelphi, MD. The conference center telephone number is 301–985–7300.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, e-mail: *ACRHD@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 9, 2011, the committees will discuss the benefits and risks of ORTHO EVRA (norelgestromin/ethinyl estradiol transdermal system), marketed by Janssen Pharmaceuticals, Inc., for the prevention of pregnancy. Specifically, the committees will discuss the possibly increased risk of thrombotic (blood clots) and thromboembolic events (blood clots that can break loose and move within the circulatory system) in users of ORTHO EVRA compared to women who use commonly prescribed birth control pills, as suggested by postmarketing studies.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 23, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 15, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 16, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 19, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–24533 Filed 9–22–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Joint Meeting of the Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committees: Advisory Committee for Reproductive Health Drugs and the Drug Safety and Risk Management Advisory Committee.

General Function of the Committees: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on December 8, 2011, from 8 a.m. to 5 p.m.

Location: The Marriott Inn and Conference Center, University of Maryland University College, The Ballroom, 3501 University Blvd. East, Adelphi, MD. The conference center telephone number is 301–985–7300.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, e-mail: *ACRHD@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On December 8, 2011, the committees will discuss the benefits and risks of drospirenone-containing oral contraceptives in light of the emerging safety concern that the risk of venous thromboembolism (blood clots that can break loose and move within the circulatory system) associated with use of these products may be higher compared to oral contraceptives that contain the progestin, levonorgestrel. Drospirenone-containing oral contraceptives for the primary indication of pregnancy prevention include: YASMIN, YAZ (drospirenone/ethinyl estradiol tablets), BEYAZ, SAFYRAL (drospirenone/ethinyl estradiol/levomefolate calcium tablets and levomefolate calcium tablets), Bayer HealthCare, and the generic equivalents for these products.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the

meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before November 23, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before November 15, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by November 16, 2011.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Kalyani Bhatt at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: September 20, 2011.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2011–24532 Filed 9–22–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0318]

Novartis Pharmaceuticals Corp. et al.; Withdrawal of Approval of 27 New Drug Applications and 58 Abbreviated New Drug Applications; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 21, 2010 (75 FR 42455). The document withdrew approval of 27 new drug applications (NDAs) and 58 abbreviated new drug applications (ANDAs) from multiple applicants. The published document excluded a footnote in the table. This document corrects that error.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3208, Silver Spring, MD 20993–0002, 301–796–9148.

SUPPLEMENTARY INFORMATION: In FR Doc. 2010–17785, appearing on page 42455, in the **Federal Register** of Wednesday, July 21, 2010, the following correction is made:

1. On page 42456, in Table 1, under the ''Drug'' column, correct the entry for ''Proventil (albuterol USP) Inhalation Aerosol'' to read ''Proventil (albuterol USP) Inhalation Aerosol [1]''.

2. On page 42456, at the end of the table, add footnote number 1 to read:

This product included an oral pressurized metered-dose inhaler that contained chlorofluorocarbons (CFCs) as a propellant. CFCs may no longer be used as a propellant for any albuterol metered-dose inhalers. (See 70 FR 17168, April 4, 2005.)

Dated: September 19, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–24400 Filed 9–22–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

National Practitioner Data Bank; Name Change of Proactive Disclosure Service (PDS) to Continuous Query

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: On March 7, 2007, the Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS), published in the **Federal Register** a notice announcing the implementation of a prototype for querying the National Practitioner Data Bank (NPDB), then known as Proactive Disclosure Service (PDS). This notice announces that the prototype status is removed and that PDS is now known as Continuous Query.

DATES: The effective date of this status upgrade and name change is September 23, 2011.

FOR FURTHER INFORMATION CONTACT: Director, Division of Practitioner Data Banks, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, 5600 Fishers Lane, Room 8–103, Rockville, MD 20857; telephone number: (301) 443–2300.

SUPPLEMENTARY INFORMATION:

I. Background

On March 7, 2007, the National Practitioner Data Bank (NPDB) published in the **Federal Register** (72 FR 10227) a notice announcing a Proactive Disclosure Service (PDS) prototype. The PDS was offered as an alternative to the traditional querying of the NPDB and allowed for on-going monitoring of a practitioner's credentials. PDS is a subscription service that notifies subscribers, which are registered entities that are eligible to query the NPDB or the Healthcare Integrity and Protection Data Bank (HIPDB), of new information on any of their enrolled practitioners within 24 hours of the NPDB or HIPDB receipt of the information. The PDS prototype was available for enrollment beginning on April 30, 2007 to a select group of NPDB registered entities. A few months later PDS was opened to all NPDB registered entities, as well as to those registered in the HIPDB. In the last year (July 1, 2010 through June 30, 2011), 1,965 entities had practitioner enrollments through PDS versus 14,370 entities that submitted traditional queries on