Keith A. Tucker,

Information Collection Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0238]

Neurological Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting; Request for Comments

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 Committee: Neurological Devices Panel of the Medical Devices Advisory Committee.

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

Date and Time: The meeting will be held on April 24, 2014, from 8 a.m. to 6 p.m.

Location: Holiday Inn, Main Ballroom, 2 Montgomery Village Ave., Gaithersburg, MD 20879. The hotel's telephone number is 301–948–8900.

Contact Person: Avena Russell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring, MD 20993–0002, *Avena.Russell@fda.hhs.gov,* 301–796–3805, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On April 24, 2014, the committee will discuss the current knowledge about the safety and effectiveness of aversive conditioning devices that are intended to deliver a noxious electrical stimulus to a patient to modify undesirable behavioral characteristics. FDA is convening this committee to seek clinical and scientific expert opinion on the risks and benefits of certain aversive conditioning devices based on available scientific data and information. The Agency is considering whether to ban aversive conditioning devices that are intended to administer a noxious electrical stimulus to a patient to modify undesirable behavioral characteristics. The meeting will concern only devices classified under 21 CFR 882.5235 (aversive conditioning device, class II) that are not self-administered. Devices which deliver a noxious electrical stimulus automatically are not considered to be self-administered devices. Section 516 of the FD&C Act (21 U.S.C. 360f) sets forth the standard for banning devices. Under that provision, in order to ban a device, FDA must make a finding that a device ''presents substantial deception or an unreasonable and substantial risk of illness or injury'' based on all available data and information. FDA regulations provide additional details about the procedures and standards for banning a device (21 CFR part 895).

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 meeting link.

Procedure: FDA will work with affected industry, professional organizations, and societies that have an interest in aversive conditioning devices and who wish to make a presentation separate from the general open public hearing; time slots on April 24, 2014, between approximately 11 a.m. and 12 p.m. Representatives from industry, professional organizations and societies interested in making formal presentations to the committee should notify the contact person on or before March 28, 2014.

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 April 14, 2014. 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 April 4, 2014. 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 April 7, 2014.

FDA is opening a docket for public comment on this document. The docket number is FDA–2014–N–0238. The docket will close on June 24, 2014. Interested persons are encouraged to use the docket to submit electronic or written comments regarding this meeting. Comments received on or before April 14, 2014, will be provided to the committee for their consideration. Comments received after May 27, 2014 will be taken into consideration by the Agency.

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

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 AnnMarie Williams at *Annmarie.Williams@fda.hhs.gov,* or 301–796–5966 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: March 20, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0021]

AbbVie Inc., et al.; Proposal To Withdraw Approval of Abbreviated New Drug Applications for Prescription Pain Medications Containing More Than 325 Milligrams of Acetaminophen; 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 abbreviated new drug applications (ANDAs) from multiple sponsors for prescription pain medications containing more than 325 milligrams (mg) of acetaminophen. The basis for this proposal is that the Agency has determined that fixed-combination prescription drugs containing more than 325 mg of acetaminophen per dosage unit (tablet or capsule) do not provide a sufficient margin of safety to protect the public against the serious risk of acetaminophen-induced liver injury.

DATES: Submit written requests for a hearing by April 28, 2014; submit data and information in support of the hearing request by May 27, 2014.

ADDRESSES: Identify your requests for a hearing, supporting data, and other comments with Docket No. FDA–2011–N–0021 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: Rachel Turow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6236, Silver Spring, MD 20993–0002, 301–796–5094.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 14, 2011 (76 FR 2691), FDA published a notice announcing its plans to reduce the maximum dosage unit strength of acetaminophen in prescription drug products. The notice announced FDA's conclusion that, based on a reevaluation of the relative risks and benefits of prescription acetaminophen products, fixed-combination prescription drugs containing more than 325 mg of acetaminophen per dosage unit (tablet or capsule) do not provide a sufficient margin of safety to protect the public against the serious risk of acetaminophen-induced liver injury. Accordingly, we asked product sponsors to limit the maximum amount of acetaminophen per dosage unit to 325 mg and, for those products containing more than 325 mg of acetaminophen per dosage unit, to submit requests that FDA withdraw approval of their applications under § 314.150(d) (21 CFR 314.150(d)). FDA asked that all such requests be made before January 14, 2014, after which date the Agency would use its authority under section 505(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(e)) to initiate approval withdrawal proceedings for any prescription drug products containing more than 325 mg of acetaminophen per dosage unit that remain on the market. The full text of that notice is provided in this document, and provides a detailed description and analysis of the specific facts resulting in today's action.

FDA did not receive a request for withdrawal of approval of an application containing more than 325 mg of acetaminophen per dosage unit from one sponsor. In addition, FDA received requests for withdrawal of approval of applications for products containing more than 325 mg of acetaminophen per dosage unit for which sponsors either submitted requests under § 314.150(c) or failed to cite a relevant regulatory provision. FDA contacted all of these sponsors on multiple occasions to ask that they submit a request that FDA withdraw approval of their applications under § 314.150(d), but they failed to respond.

With respect to those applications for which FDA received no request for withdrawal, FDA is proceeding under § 314.150(a) and (b) to withdraw approval. With respect to requests for withdrawal of approval submitted under § 314.150(c), the Agency notes that because FDA has made a determination under § 314.150(a) that approval of these applications should be withdrawn for reasons of safety, application holders may not withdraw their applications pursuant to § 314.150(c). The text of § 314.150(c) expressly precludes withdrawal of an application under the subsection if FDA has made a safety determination under § 314.150(a). Similarly, when a request for withdrawal is made without a citation to any regulation, FDA is not appropriately notified that an application holder has voluntarily waived the opportunity for a hearing. Accordingly, FDA has determined to proceed with withdrawal of approval of applications for which sponsors either submitted requests under § 314.150(c) or failed to cite a relevant regulatory provision pursuant to the withdrawal procedures outlined in §§ 314.150 (a) and (b).

Table 1 lists the applications for products for which FDA received no request for withdrawal, a request for withdrawal citing § 314.150(c), or a request for withdrawal with no regulatory citation.

TABLE 1—APPLICATIONS FOR FIXED-COMBINATION PRESCRIPTION DRUGS CONTAINING MORE THAN 325 MG OF ACETAMINOPHEN PER DOSAGE UNIT THAT HAVE NOT BEEN VOLUNTARILY WITHDRAWN AS OF JANUARY 14, 2014

Application No.	Drug product(s)	Applicant or holder	Reason
ANDA 40117	Vicodin HP (Acetaminophen and Hydrocodone Bitartrate Tablets), 660 mg/10 mg.	AbbVie Inc., 1 N. Waukegan Rd., North Chicago, IL 60064.	Submitted a voluntary request for withdrawal under § 314.150(c).
ANDA 88058	Vicodin (Acetaminophen and Hydrocodone Bitartrate Tablets), 500 mg/5 mg.	AbbVie Inc	Submitted a voluntary request for withdrawal under § 314.150(c).
ANDA 89736	Vicodin ES (Acetaminophen and Hydrocodone Bitartrate Tablets), 750 mg/7.5 mg.	AbbVie Inc	Submitted a voluntary request for withdrawal under § 314.150(c).