

suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug that has been voluntarily withdrawn from sale was withdrawn for reasons of safety or effectiveness. This determination may be made at any time after the drug has been voluntarily withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, is the subject of ANDA 83-296, held by Allergan Herbert (Allergan) and initially approved on June 15, 1973. AEROSEB-DEX is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

In its June 1997 annual report, Allergan notified FDA that AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. In a letter dated August 28, 1998, Allergan requested withdrawal of ANDA 83-296 for AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%. In the **Federal Register** of June 10, 1999 (64 FR 31226), FDA announced that it was withdrawing approval of ANDA 83-296, effective July 12, 1999.

Acaderm Inc., (Acaderm) submitted a citizen petition dated April 28, 2005 (Docket No. FDA-2005-P-0394), under 21 CFR 10.30, requesting that the Agency determine whether AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, was withdrawn from sale for reasons of safety or effectiveness. Although the citizen petition did not address DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, that dexamethasone topical aerosol product has also been discontinued. On our own initiative, we have also determined whether DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, was withdrawn for safety or effectiveness reasons.

DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, is the subject of NDA 12-731, held by Merck & Co., Inc. (Merck). DECASPRAY, a synthetic adrenocortical steroid, was initially approved on March 29, 1961, solely on the basis of safety. The 1962 amendments to the FD&C Act require that drugs be shown to be effective as

well. To accomplish this, FDA initiated the Drug Efficacy Study Implementation (DESI) review to evaluate the effectiveness of drugs that had been previously approved on safety grounds alone. In its DESI review of topical corticosteroids, FDA concluded that NDA 12-731 for dexamethasone topical aerosol was effective for certain indications (*see* 36 FR 7982, April 28, 1971), and it was labeled for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

In its annual report, Merck notified FDA that DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book. In a letter dated June 25, 2002, Merck requested withdrawal of NDA 12-731 for DECASPRAY (dexamethasone) Topical Aerosol, 0.04%. In the **Federal Register** of August 18, 2003 (68 FR 49481), FDA announced that it was withdrawing approval of NDA 12-731, effective September 17, 2003.

After considering the citizen petition and comments submitted to the docket, and reviewing Agency records, FDA has determined under § 314.161 that AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, from sale and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

FDA has also determined under § 314.161 that DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, was not withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list DECASPRAY (dexamethasone) Topical Aerosol,

0.04%, and AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, and AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, may be approved by the Agency as long as they meet all other legal and regulatory requirements for approval of ANDAs. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

In considering whether to file an ANDA for this drug product, future applicants should be advised that they may not be able to obtain DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, or AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, for bioequivalence testing because the products have not been commercially available for a number of years. An ANDA applicant who is unable to obtain DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, or AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, for bioequivalence testing should contact the Office of Generic Drugs for a determination of what showing is necessary to satisfy the requirements of section 505(j)(2)(A)(iv) of the FD&C Act. If an ANDA is approved without a showing of bioequivalence, the approved product will not be considered therapeutically equivalent to the reference listed drug, *i.e.*, granted an AB rating, in the Orange Book.

Dated: February 3, 2011.

**David Dorsey,**

*Acting Deputy Commissioner for Policy, Planning and Budget.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2011-N-0063]

### Medical Device Innovation Initiative; Request for Comments

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document for public comment entitled “Medical Device Innovation Initiative” (the report). The report proposes potential actions for FDA’s Center for Devices and Radiological Health (CDRH) to facilitate the development, assessment, and regulatory review of innovative medical devices.

**DATES:** Submit either electronic or written comments on the report by April 11, 2011.

**ADDRESSES:** See the **SUPPLEMENTARY INFORMATION** section for electronic access to the report.

Submit electronic comments on the report to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Jonathan Sackner-Bernstein, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5410, Silver Spring, MD 20993, 301-796-5420, e-mail: [jonathan.sackner-bernstein@fda.hhs.gov](mailto:jonathan.sackner-bernstein@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The United States is the global leader in medical device innovation and CDRH is committed to assuring that American patients have timely access to important new technologies and next-generation products without compromising their safety. Each year, millions of American patients benefit from innovative medical devices that reduce suffering, treat previously untreatable conditions, extend lives, and improve public health.

CDRH is responsible for advancing public health and facilitating innovation to help bring novel technologies to market and make the medical devices that are already on the market safer and more effective. Recently, CDRH announced 25 actions it will take in 2011 to strengthen its most widely-used premarket review process—the 510(k) program—and increase its use of emerging science to foster innovation and improve the predictability, consistency, and transparency of its decisionmaking.<sup>1</sup> These actions will not

only improve the safety of medical devices but also increase the ability of innovating companies to attract investors, estimate costs, and more quickly bring products to market.

The report proposes actions CDRH might take to help accelerate the development and regulatory evaluation of innovative devices safely and based on sound science. These actions are as follows:

- Facilitate the development and regulatory evaluation of innovative medical devices;
- Strengthen the U.S. research infrastructure and promote high-quality regulatory science; and
- Prepare for and respond to transformative innovative technologies and scientific breakthroughs.

Part of the Medical Device Innovation Initiative would consider the creation of a special Innovation Pathway intended to provide earlier investment of CDRH time and resources in devices that are true pioneering technologies and that have the potential to revolutionize patient care or health care delivery. By front-loading critical aspects, such as identifying clinical endpoints and key scientific questions, and seeking advice from external experts, the Innovation Pathway would facilitate a more efficient regulatory review process for transformative devices.

CDRH is seeking public comment on the proposals contained in the report through an open public docket and will be hosting a public meeting to solicit stakeholder feedback at our White Oak, MD campus on March 15, 2011. Therefore, elsewhere in this issue of the **Federal Register**, FDA is announcing a public meeting entitled “CDRH’s Medical Device Innovation Initiative Public Workshop.”

CDRH requests public comments on the report in general, as well as the following specific questions and topics:

1. The eligibility criteria for the Innovation Pathway.
2. How should CDRH determine what types of technology should be allowed into the Innovation Pathway and at what point they should no longer be accepted as innovative products? For example, under Expedited Review, if multiple applications for the same type of device offering comparable advantage over existing approved alternatives have been granted expedited review, they are reviewed with priority assigned on a first-in-first-reviewed basis for each review cycle. Furthermore, if one of

these applications is approved, the remaining expedited applications will retain their expedited status until a final decision is rendered after which point no additional devices of this type will be granted expedited review status. Should the same process be used for the Innovation Pathway?

3. What are the appropriate timeframes for review of submissions under the Innovation Pathway? Should final regulatory submissions from devices developed under the Innovation Pathway be reviewed on a shortened timeframe? For comparison, the review times to which CDRH has currently committed under the Medical Device User Fee and Modernization Act are available at: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109319.htm>.

4. Criteria for clinical test center certification.

5. Candidates for interagency or public-private partnerships to foster medical device innovation.

6. Other actions CDRH should take to facilitate the development, assessment, and regulatory review of innovative medical devices while assuring their safety and effectiveness.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (*see ADDRESSES*) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

**III. Electronic Access**

Persons with access to the Internet may obtain the report at <http://www.regulations.gov> or <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm241095.htm>.

Dated: February 4, 2011.

**Nancy K. Stade,**

*Deputy Director, Center for Devices and Radiological Health.*

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<sup>1</sup> See “510(k) and Science Report Recommendations: Summary and Overview of Comments and Next Steps,” available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239449.pdf>; and “Plan of Action for

Implementation of 510(k) and Science Recommendations,” available at <http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf>.