1. The impact on physicians, their patients, and their practices of the disclosure of still uncertain, emerging risks associated with medical products.

2. How physicians currently receive and ideally would like to receive new risk information about medical products (for example, at what level of certainty regarding causality and through what communication channels).

3. How physicians perceive the trustworthiness of FDA and other potential sources of risk information, including product sponsors, medical societies, and the media.

4. What FDA might do to increase the likelihood that respondents will report to FDA or to manufacturers serious patient reactions that might be side effects of using medical products.

In the **Federal Register** of July 31, 2006 (71 FR 43200), FDA published a 60-day notice requesting public comment on the information collection provisions. Comments were received from five public entities consisting of two corporations and three associations. Comments supported FDA's belief in the value of conducting the survey. None of the comments addressed specific survey questions. FDA agrees with the comments concerning the study methodology.

- Questions should be clear and not leading or ambiguous.
- FDA should conduct pre-tests.
- The sample size will be sufficient to provide statistically relevant information for the two stratified segments of physicians and the combination of these segments.

After carefully considering them, FDA determined that other comments would require changes that would reduce the utility of study results by diluting the study's focus, omitting important topic areas, or making the questionnaire excessively long and thereby reducing response rates. These comments included the following:

- Including other health care providers ''who prescribe drugs.''
- Getting more detail about particular source categories.
- Omitting questions about how respondents report adverse events or product problems.

FDA agreed with the value of adding some questions that ask about the inclusion of other information, including benefits, in communications about newly emerging product risks.

FDA also received feedback from experts in the fields of risk communication and health literacy on the study and the proposed questionnaire at an ''Effective Risk Communication'' Think Tank Workshop. FDA revised the survey questionnaire in response to this feedback, the feedback received through the public comments, and eight cognitive interviews conducted in May 2007.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
27 (Pretests)	1	27	.3	8.1
1,000 (Screener)	1	1,000	.025	25.0
900 (Survey)	1	900	.25	225.0
Total				258.1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

These estimates are based on FDA's and the contractor's experience with previous surveys. The respondents are divided into two groups: Primary care physicians and specialist physicians. We are basing this estimate on 90 percent of the screened physicians being eligible to participate in the survey.

Prior to administering the survey with the entire sample, FDA plans to conduct pretests with up to 27 physicians; these are meant to evaluate the clarity and consistency of the survey questionnaire and interview protocol.

Dated: July 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–14015 Filed 7–18–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007P–0052]

Determination That Brethine (Terbutaline Sulfate) Injection Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its determination that Brethine (Terbutaline Sulfate) Injection was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for terbutaline sulfate injection if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Carol E. Drew, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the ''listed drug,'' which is a version of the drug that was previously approved under a new drug application (NDA). ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of an NDA. The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal

Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the ''Approved Drug Products With Therapeutic Equivalence Evaluations,'' which is known generally as the ''Orange Book.'' Under FDA regulations, drugs are removed from the list if the agency withdraws or 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). Regulations also provide that the agency must make a determination as to whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (§ 314.161(a)(1) (21 CFR 314.161(a)(1))). FDA may not approve an ANDA that does not refer to a listed drug.

On February 9, 2007, West-ward Pharmaceutical Corp. (West-ward), on behalf of Hikma Farmaceutica (Portugal), S.A., submitted a citizen petition (Docket No. 2007P–0052/CP1) to FDA under 21 CFR 10.30. The petition requests that the agency determine whether Brethine (terbutaline sulfate) injection (NDA 18–571), manufactured by AaiPharma, was withdrawn from sale for reasons of safety or effectiveness. AaiPharma ceased manufacture of Brethine injection and it was moved from the prescription drug product list to the ''Discontinued Drug Product List'' section of the Orange Book in August of 2006.

Brethine injection was first approved in 1981; this approval was for a glass ampoule container closure system. In 2004 AaiPharma received approval of a glass vial container closure system for a Brethine injection formulation that contained 0.055 percent disodium edetate. When Brethine injection was discontinued, an approved generic was chosen as the replacement reference listed drug. The replacement reference listed drug does not contain 0.055 disodium edetate and is based on the original glass ampoule formulation. Therefore, West-ward requests that the agency make a determination that the reformulated version of Brethine injection was not withdrawn for safety or efficacy reasons.

FDA has reviewed its records and, under § 314.161, has determined that Brethine (terbutaline sulfate) injection was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified no data or other information suggesting that Brethine containing 0.055 disodium edetate was withdrawn for reasons of safety or effectiveness. FDA has independently evaluated relevant literature and data for possible postmarketing adverse events and has found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Furthermore we have determined that the change in formulation was not for safety or efficacy reasons. Our files indicate that disodium edetate was added as a protectant against certain oxidation-derived terbutaline impurities and degradants when the manufacturing site and container closure system were changed. Accordingly, the agency will continue to list terbutaline sulfate injection 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 terbutaline sulfate injection may be approved by the agency if all other legal and regulatory requirements for the approval of ANDAs are met. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: July 12, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–13950 Filed 7–18–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0201]

Draft Guidance for Industry and Food and Drug Administration Staff; Premarket Notification Submissions for Medical Devices That Include Antimicrobial Agents; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Premarket Notification (510(k)) Submissions for Medical Devices That Include Antimicrobial Agents.'' This draft guidance is intended to assist device manufacturers interested in preparing premarket notification (510(k)) submissions for their medical devices that include antimicrobial agents. This guidance recommends testing and labeling for 510(k) submissions for devices that include antimicrobial agents. It is intended as a supplement to other device-specific guidance issued by the Center for Devices and Radiological Health (CDRH).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 17, 2007.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Premarket Notification (510(k)) Submissions for Medical Devices That Include Antimicrobial Agents'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Michelle Rios, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3747.

SUPPLEMENTARY INFORMATION:

I. Background

In recent years there has been increased interest in adding antimicrobial agents to medical devices for specific or limited indications for use, such as reduction or prevention of a device-related infection, or reduction or inhibition of colonization of a medical device. FDA developed this draft guidance to assist device manufacturers in preparing premarket notification (510(k)) submissions for medical devices that include antimicrobial agents.