September 30, 2011. Consistent with the statute and regulations, ACF requests revision of the ACF 118–A with minor corrections and modifications.

The Office of Child Care (OCC) has given thoughtful consideration to the comments received from the 1st Public Notice. OCC has revised the document to reflect some of the changes made to minimize the burden of the collection of information on respondents. The revised document contains revisions to improve the accuracy and clarity of questions in order to improve the quality of information that is collected. This second Public Comment Period provides an opportunity for the public to submit comments to the Office of Management and Budget (OMB).

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

Respondents:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF Tribal Plan	257	0.5	120	15,420
Estimated Total Annual Burden Hours				15,420

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7285, E-mail: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Dated: February 2, 2011.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–2798 Filed 2–8–11; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2005–P–0394] (formerly Docket No. 2005P–0168)

Determination That DECASPRAY (Dexamethasone) Topical Aerosol, 0.04%, and AEROSEB-DEX (Dexamethasone) Topical Aerosol, 0.01%, Were 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) has determined that DECASPRAY (dexamethasone) Topical Aerosol, 0.04%, and AEROSEB-DEX (dexamethasone) Topical Aerosol, 0.01%, were not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for dexamethasone topical aerosol, 0.04% and 0.01%, if all other legal and regulatory requirements are met. However, in considering whether to file an ANDA for dexamethasone topical aerosol, 0.04% and 0.01%, future applicants are 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 is necessary to show bioavailability and same therapeutic effect.

FOR FURTHER INFORMATION CONTACT: Janice Weiner, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6304, Silver Spring, MD 20993–0002, 301–796–3601.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products 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. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (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 (FD&C 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).

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.

[FR Doc. 2011–2890 Filed 2–8–11; 8:45 am]

BILLING CODE 4160–01–P

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.