

- Ensure adequate and timely reporting of program data to relevant federal agencies and stakeholders including the Congress, and members of the public.

Tribal HV Form 2 will provide a template for Tribal MIECHV grantees to report data on their progress under the six benchmark areas as stipulated in legislation.

Respondents: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Tribal Maternal, Infant, and Early Childhood Home Visiting Performance Reporting Form	20	1	500	10,000

Estimated Total Annual Burden Hours: 10,000.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C St. SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Mary Jones,
ACF/OPRE Certifying Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-P-0377]

Determination That ACTHAR GEL SYNTHETIC (Seractide Acetate) Injection, 80 Units/Milliliter and 40 Units/Milliliter, Was Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) has determined that ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/milliliter (mL) and 40 units/mL, was withdrawn from sale for reasons of safety or effectiveness. The Agency will not accept or approve abbreviated new drug applications (ANDAs) for seractide acetate injection, 80 units/mL and 40 units/mL.

FOR FURTHER INFORMATION CONTACT: David E. Markert, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6222, Silver Spring, MD 20993-0002, 301-796-0752.

SUPPLEMENTARY INFORMATION:

I. Background

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 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic 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 was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (21 CFR 314.161). FDA may not approve an ANDA that does not refer to a listed drug.

ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL was the subject of NDA 017861, which was held by Armour Pharmaceutical Co. (Armour), and initially approved on February 21, 1978. ACTHAR GEL SYNTHETIC is indicated for diagnostic testing of adrenocortical function. The labeling also provides that ACTHAR GEL SYNTHETIC may be employed in the following disorders:

Endocrine Disorders: Nonsuppurative thyroiditis; Hypercalcemia associated with cancer.

Nervous System Diseases: Acute exacerbations of multiple sclerosis.

Rheumatic Disorders: As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in: Psoriatic arthritis; rheumatoid arthritis, including juvenile

rheumatoid arthritis (selected cases may require low-dose maintenance therapy); ankylosing spondylitis; acute and subacute bursitis; acute non-specific tenosynovitis; acute gouty arthritis; post-traumatic arthritis; synovitis of osteoarthritis; epicondylitis.

Collagen Diseases: During an exacerbation or as maintenance therapy in selected cases of: Systemic lupus erythematosus; systemic dermatomyositis (polymyositis); acute rheumatic carditis.

Dermatologic Diseases: Pemphigus; bullous dermatitis herpetiformis; severe erythema multiforme (Stevens-Johnson syndrome); exfoliative dermatitis; severe psoriasis; severe seborrheic dermatitis; mycosis fungoides.

Allergic States: Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment—seasonal or perennial allergic rhinitis; bronchial asthma; contact dermatitis; atopic dermatitis; serum sickness.

Ophthalmic Diseases: Severe acute and chronic allergic and inflammatory processes involving the eye and its adnexa such as: Allergic conjunctivitis; keratitis; herpes zoster ophthalmicus; iritis and iridocyclitis; diffuse posterior uveitis and choroiditis; optic neuritis; sympathetic ophthalmia; chorioretinitis; anterior segment inflammation; allergic corneal marginal ulcers.

Respiratory Diseases: Symptomatic sarcoidosis; Loeffler's syndrome not manageable by other means; berylliosis; fulminating or disseminated pulmonary tuberculosis when used concurrently with anti-tuberculous chemotherapy; aspiration pneumonitis.

Hematologic Disorders: Acquired (autoimmune) hemolytic anemia; secondary thrombocytopenia in adults; erythroblastopenia (RBC anemia); congenital (erythroid) hypoplastic anemia.

Neoplastic Diseases: For palliative management of: Leukemias and lymphomas in adults; acute leukemia of childhood.

Edematous State: To induce a diuresis or a remission of proteinuria in the nephrotic syndrome without uremia of the idiopathic type or that due to lupus erythematosus.

Gastrointestinal Diseases: To tide the patient over a critical period of the disease in: Ulcerative colitis; regional enteritis.

Miscellaneous: Tuberculous meningitis with subarachnoid block or impending block when concurrently accompanied by appropriate anti-tuberculous chemotherapy; trichinosis with neurologic or myocardial involvement.

Armour never marketed ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL. In previous instances (see, e.g., 72 FR 9763, March 5, 2007 and 61 FR 25497, May 21, 1996), the Agency has determined that for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale. FDA withdrew approval of the NDA for ACTHAR GEL SYNTHETIC in 2014 because Armour had repeatedly failed to file annual reports for the application (79 FR 68454, November 17, 2014).

Hyman, Phelps & McNamara, P.C., submitted a citizen petition dated April 1, 2014 (Docket No. FDA-2014-P-0377), under 21 CFR 10.30, requesting that the Agency determine whether ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL, was withdrawn from sale for reasons of safety or effectiveness.

II. Response to Citizen Petition

We have carefully reviewed the citizen petition (and comments submitted to the docket); our records for ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL; the scientific literature on seractide acetate; and other relevant information. Based on that review, and for the reasons set forth in this section, we have concluded that additional studies of safety would be necessary before ACTHAR GEL SYNTHETIC could be considered for introduction to the market today. Consequently, FDA has determined under § 314.161 that ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL, was withdrawn for reasons of safety.¹

The labeling for ACTHAR GEL SYNTHETIC describes the product as “a highly purified synthetic polypeptide containing thirty-nine amino acids in the sequence described for human corticotropin by Lee, T.H.; Lerner, A.B.; and Buettner-Janusch, Vina (J. Biol. Chem, 236:2970–2974, Nov. 1961)” (Refs. 1 and 2). At the time of ACTHAR GEL SYNTHETIC's approval, FDA believed the amino acid sequence described by Lee et al. was the correct sequence for human corticotropin and, therefore, that ACTHAR GEL SYNTHETIC was identical to human

corticotropin.² However, since approval, the Agency has learned that ACTHAR GEL SYNTHETIC is not identical to the human corticotropin sequence. We now know that the amino acid sequence described by Lee et al. is a deamidated version of human corticotropin that differs from full length human corticotropin at four positions.³

The fact that ACTHAR GEL SYNTHETIC has a different amino acid sequence from human corticotropin raises significant safety concerns. Due to its different amino acid sequence, ACTHAR GEL SYNTHETIC might have a structure or function that is not recognized as endogenous by the immune system. ACTHAR GEL SYNTHETIC thus poses a higher risk of immunogenicity than a synthetic peptide product that is, in fact, identical to human corticotropin. The health consequences of immunogenicity range from subacute, minor reactions to severe, even deadly, reactions (e.g., anaphylaxis). In addition, frequent stimulation of the immune system could produce antibodies that cross-react with human corticotropin and other closely related endogenous peptides, resulting in the loss of those peptides' physiological functions. Such an effect could last long after treatment with ACTHAR GEL SYNTHETIC has stopped.

The safety concerns noted in this section have not been adequately investigated. ACTHAR GEL SYNTHETIC was studied in two clinical trials in 51 healthy adult men between 21 and 54 years old. Although no unusual adverse effects were reported during these trials, the trials did not assess the impact of immunogenicity on safety. Nor were they designed to assess immunogenicity. Moreover, because ACTHAR GEL SYNTHETIC was never marketed, the Agency has no postmarketing safety data or information confirming that the product is safe for human use, notwithstanding the differences between ACTHAR GEL SYNTHETIC's amino acid sequence and that of human corticotropin. Given the lack of any premarket or postmarket

² The Agency's Institutional Summary of Basis of Approval (Ref. 3) describes ACTHAR GEL SYNTHETIC as “a synthetic peptide of 39 amino acids identical with that of natural human” corticotropin.

³ The record for human pro-opiomelanocortin preproprotein in the National Center for Biotechnology Information's “Protein” database (Reference Sequence NP_000930.1) contains the correct amino acid sequence for human corticotropin. The record is available at the following URL: https://www.ncbi.nlm.nih.gov/protein/NP_000930.1. The sequence described by Lee et al. differs from the correct sequence at positions 25–27 and 30.

¹ In light of this conclusion, it is unnecessary for us to determine whether ACTHAR GEL SYNTHETIC was also withdrawn from sale for reasons of effectiveness. This notice does not address the effectiveness of ACTHAR GEL SYNTHETIC for its labeled indications.

immunogenicity safety data, FDA cannot conclude that ACTHAR GEL SYNTHETIC would be safe for human use if it were introduced to the market today.

Accordingly, the Agency will remove ACTHAR GEL SYNTHETIC (seractide acetate) injection, 80 units/mL and 40 units/mL, from the list of drug products published in the Orange Book. FDA will not accept or approve ANDAs that refer to this drug product.

III. References

The following references have been placed on display in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at <https://www.regulations.gov>.

1. Armour Pharmaceutical Co., "ACTHAR® Gel Synthetic (SERACTIDE ACETATE), Synthetic Corticotropin," Product Labeling, 1979.
2. Lee, T. H., A. B. Lerner, and V. Buettner-Janusch, "On the Structure of Human Corticotropin (Adrenocorticotrophic Hormone)," *The Journal of Biological Chemistry*, vol. 236, pp. 2970-2974, 1961.
3. FDA, "Seractide Acetate: Institutional Summary of Basis of Approval," August 22, 1977.

Dated: January 13, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-01249 Filed 1-19-17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0825]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by February 22, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0231. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Premarket Approval of Medical Devices—OMB Control Number 0910-0231—Extension

Under section 515 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e) all devices placed into class III by FDA are subject to premarket approval (PMA) requirements. PMA is the process of scientific and regulatory review to ensure the safety and effectiveness of class III devices. An approved PMA is, in effect, a private license granted to the applicant for marketing a particular medical device. A class III device that fails to meet PMA requirements is considered to be adulterated under section 501(f) of the FD&C Act (21 U.S.C. 351(f)) and cannot be marketed. PMA requirements apply differently to preamendments devices, postamendments devices, and transitional class III devices.

Manufacturers of class III preamendments devices, devices that were in commercial distribution before May 28, 1976, are not required to submit a PMA until 30 months after the issuance of a final classification regulation or until 90 days after the publication of a final regulation requiring the submission of a PMA, whichever period is later. FDA may allow more than 90 days after issuance of a final rule for submission of a PMA.

A postamendments device is one that was first distributed commercially on or after May 28, 1976. Postamendments devices determined by FDA to be substantially equivalent to preamendments class III devices are subject to the same requirements as the preamendments devices. FDA

determines substantial equivalence after reviewing an applicant's premarket notification submitted in accordance with section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Postamendments devices determined by FDA to be not substantially equivalent to either preamendments devices or postamendments devices classified into class I or II are "new" devices and fall automatically into class III. Before such devices can be marketed, they must have an approved PMA application or be must reclassified into class I or class II.

The Food and Drug Modernization Act of 1997 (FDAMA) (Pub. L. 105-115) was enacted on November 21, 1997, to implement revisions to the FD&C Act by streamlining the process of bringing safe and effective drugs, medical devices, and other therapies to the U.S. market. FDAMA added section 515(d)(6) to the FD&C Act (21 U.S.C. 360e(d)(6)), which provided that PMA supplements were required for all device changes that affect safety and effectiveness unless such changes are modifications to manufacturing procedures or method of manufacture. That type of manufacturing change will require a 30-day notice, or where FDA finds such notice inadequate, a 135-day PMA supplement.

The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a PMA for a medical device and the criteria FDA will employ in approving, denying, or withdrawing approval of a PMA and supplements to PMAs. The regulations' purpose is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for class III medical devices. The regulations facilitate the approval of PMAs and supplements to PMAs for devices that have been shown to be reasonably safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure the denial of PMAs and supplements to PMAs for devices that have not been shown to be reasonably safe and effective and that do not otherwise meet the statutory criteria for approval.

The industry-wide burden estimate for PMAs is based on an FDA average fiscal year (FY) annual rate of receipt of PMA submissions data FYs 2013 through 2015 and our expectation of submissions to come in the next few years. The burden data for PMAs is based on data provided by applicants by device type and cost element in an earlier study.

Reporting Burden: The reporting burden can be broken out by certain