The sponsors of covered studies will be required to maintain complete records of compensation agreements with any compensation paid to nonemployee clinical investigators, including information showing any financial interests held by the clinical investigator, for a time period of 2 years after the date of approval of the applications. This time is consistent with the current recordkeeping requirements for other information related to marketing applications for human drugs, biologics, and medical devices. Currently, sponsors of covered studies must maintain many records with regard to clinical investigators, including protocol agreements and investigator resumes or curriculum vitae. FDA estimates than an average of 15 minutes will be required for each recordkeeper to add this record to clinical investigators' file.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours Per Recordkeeper	Total Hours
54.6	1,000	1	1,000	.25	250
Total					250

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

In the **Federal Register** of August 25, 2005 (70 FR 49928), FDA announced the availability of the draft guidance and requested comments for 60 days on the information collection. No comments were received regarding this information collection.

Dated: February 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1807 Filed 2–9–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005N–0425]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions

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 March 13, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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.

General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions—(OMB Control Number 0910–0183)—Extension

The Administrative Procedures Act (5 U.S.C. 553(e)), provides that every agency shall give an interested person the right to petition for issuance, amendment, or repeal of a rule. Under part 10 (21 CFR part 10), § 10.30 sets forth the format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (submission of documents to the Division of Dockets Management (DDM)), a citizen petition requesting the Commissioner of Food and Drugs (the Commissioner) to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action.

The Commissioner may grant or deny such a petition, in whole or in part, and may grant such other relief or take other action as the petition warrants. Respondents are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions or groups.

Section 10.33, issued under section 701(a) of the Federal, Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 371(a)), sets forth the format and procedures by which an interested person may request reconsideration of part or all of a decision of the Commissioner in a petition submitted under § 10.25 (initiation of administrative proceedings). A petition for reconsideration must contain in a well-organized format a full statement of the factual and legal grounds upon which the petition relies. The grounds must demonstrate that relevant information and views contained in the administrative record were not previously or not adequately considered by the Commissioner. The respondent must submit a petition no later than 30 days after the decision has been made. However, the Commissioner may, for good cause, permit a petition to be filed after 30 days. An interested person who wishes to rely on information or views not included in the administrative record shall submit them with a new petition to modify the decision. FDA uses the information provided in the request to determine whether to grant the petition for reconsideration. Respondents to this collection of information are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions who are requesting a reconsideration of a matter from the Commissioner.

Section 10.35, issued under section 701(a) of the act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (submission of documents to DDM), the Commissioner to stay the effective date of any administrative action.

Such a petition must provide the following information: (1) The decision involved; (2) the action requested, including the length of time for which a stay is requested; and (3) a statement

of the factual and legal grounds on which the interested person relies in seeking the stay. FDA uses the information provided in the request to determine whether to grant the petition for a stay of action. Respondents to this information collection are interested persons who choose to file a petition for an administrative stay of action.

Section 10.85, issued under section 701(a) of the act, sets forth the format and procedures by which an interested person may request, in accordance with § 10.20 (submission of documents to the DDM), an advisory opinion from the Commissioner on a matter of general applicability. An advisory opinion represents the formal position of FDA on a matter of general applicability. When making a request, the petitioner must provide a concise statement of the issues and questions on which an opinion is requested, and a full statement of the facts and legal points relevant to the request. Respondents to this collection of information are interested persons seeking an advisory opinion from the Commissioner on the agency's formal position for matters of general applicability.

In the **Federal Register** of November 16, 2005 (70 FR 69574), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
10.30	156	3	468	12	5,616
10.33	10	2	20	10	200
10.35	13	2	26	10	260
10.85	2	1	2	16	32
Total					6,108

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

Dated: February 6, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1846 Filed 2–9–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P–0104]

Determination That PEPTAVLON (Pentagastrin) for Subcutaneous Injection, 0.25 Milligrams per Milliliter, 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) has determined that PEPTAVLON (pentagastrin) for subcutaneous injection, 0.25 milligrams (mg) per milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for pentagastrin for subcutaneous injection, 0.25 mg/mL.

FOR FURTHER INFORMATION CONTACT: Tawni B. Schwemer, 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 sponsors 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 typically a version of the drug that was previously approved. Sponsors of ANDAs 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 (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 generally known as the ''Orange Book.'' Under FDA regulations, drugs are withdrawn 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).

PEPTAVLON for subcutaneous injection is the subject of approved NDA 17–048 held by Wyeth Ayerst Laboratories (Wyeth Ayerst). PEPTAVLON (pentagastrin) for subcutaneous injection is a testing agent to help diagnose problems or diseases of the stomach. This test determines how much acid a patient's stomach produces.

PEPTAVLON for subcutaneous injection, 0.25 mg/mL, was approved on July 26, 1974. Wyeth Ayerst ceased manufacture of PEPTAVLON for subcutaneous injection, 0.25 mg/mL, in March 2002, and requested that FDA withdraw approval of the NDA (68 FR 49481, August 18, 2003). Therefore, it was moved from the ''Prescription Drug Product List'' to 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.

Under 21 CFR 314.161(a)(3), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness when a person petitions for such a determination under 21 CFR 10.25(a) and § 10.30 (21 CFR 10.30).

Arnall Golden Gregory LLP submitted a citizen petition dated March 7, 2005 (Docket No. 2005P–0104/CP1), under § 10.30, requesting that the agency determine whether PEPTAVLON (pentagastrin) for subcutaneous injection, 0.25 mg/mL, was withdrawn from sale for reasons of safety or effectiveness. After considering the citizen petition and reviewing agency records, FDA has determined that PEPTAVLON for subcutaneous injection, 0.25 mg/mL, approved under NDA 17–048, was not withdrawn from sale for reasons of safety or effectiveness. The petitioner identified