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Determination That PEPTAVLON (Pentagastrin) for Subcutaneous Injection, 0.25 Milligrams per Milliliter, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness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determined that PEPTAVLON (pentagastrin) for subcutaneous injection, 0.25 milligrams (mg) per milliliter (mL), was not withdrawn from sale for reasons of safety or effectiveness.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

no data or other information suggesting that PEPTAVLON (pentagastrin) for subcutaneous injection, 0.25 mg/mL, was withdrawn from sale as a result of safety or effectiveness concerns. FDA's independent evaluation of relevant literature and data has not uncovered anything that would indicate that this product was withdrawn for reasons of safety or effectiveness. Accordingly, the agency will continue to list PEPTAVLON (pentagastrin) for subcutaneous injection, 0.25 mg/mL, in the ''Discontinued Drug Product List'' section of the Orange Book. ANDAs that refer to PEPTAVLON for subcutaneous injection, 0.25 mg/mL, may be approved by the agency.

Dated: February 2, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1847 Filed 2–9–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[CGD08–06–003]

Houston/Galveston Navigation Safety Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of meetings.

SUMMARY: The Houston/Galveston Navigation Safety Advisory Committee (HOGANSAC) and its working groups will meet to discuss waterway improvements, aids to navigation, area projects impacting safety on the Houston Ship Channel, and various other navigation safety matters in the Galveston Bay area. All meetings will be open to the public.

DATES: The next meeting of HOGANSAC will be held on Thursday, February 23, 2006 at 1 p.m. The meeting of the Committee's working groups will be held on Thursday, February 9, 2006 at 9 a.m. The meetings may adjourn early if all business is finished. Members of the public may present written or oral statements at either meeting. Requests to make oral presentations or distribute written materials at the full HOGANSAC meeting should reach the Coast Guard five (5) working days before that meeting. Requests to have written materials distributed to each member of the full committee in advance of their meeting should reach the Coast Guard at least ten (10) working days before the full HOGANSAC meeting.

ADDRESSES: The full Committee meeting will be held at the Charles P. Doyle Convention Center, 2010 5th Avenue North, Texas City, Texas 77590, (409–948–3111). The working groups meeting will be held at Coast Guard Sector Houston-Galveston, 9640 Clinton Dr. Houston, TX 77029 (713–671–5100). This notice is available on the Internet at *http://dms.dot.gov*.

FOR FURTHER INFORMATION CONTACT: Captain Richard Kaser, Executive Director of HOGANSAC, telephone (713) 671–5199, Commander Jerry Torok, Executive Secretary of HOGANSAC, telephone (713) 671–5164, or Lieutenant Junior Grade Kevin Cooper, Assistant to the Executive Secretary of HOGANSAC, telephone (713) 678–9001, e-mail *kcooper@grugalveston.uscg.mil*. Written materials and requests to make presentations should be sent to Commanding Officer, Sector Houston/Galveston, Attn: LTJG Cooper, 9640 Clinton Drive, Houston, TX 77029.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given pursuant to the Federal Advisory Committee Act, 5 U.S.C. App. 2.

Agendas of the Meetings

Houston/Galveston Navigation Safety Advisory Committee (HOGANSAC). The tentative agenda includes the following:

(1) Opening remarks by the Committee Sponsor (RADM Duncan) or the Committee Sponsor's representative, Executive Director (CAPT Kaser) and Chairperson (Ms. Patricia Clark).

(2) Approval of the October 18, 2005 minutes.

(3) Old Business:

(a) Dredging projects.

(b) AtoN Knockdown Working Group.

(c) Navigation Operations subcommittee report.

(d) Area Maritime Security Committee Liaison's report.

(e) Technology subcommittee report.

(f) Deep draft Entry Facilitation Working Group.

(g) Port Coordination Team Updates.

(h) Limited Visibility Working Group.

(i) Liquified Natural Gas Working Group.

(4) New Business.

(a) Vessel Traffic Service State of the Waterways Address.

(b) Swearing in of new member.

(c) Other presentations/New business.

Working Groups Meeting. The tentative agenda for the working groups meeting includes the following:

(1) Presentation by each working group of its accomplishments and plans for the future.

(2) Review and discuss the work completed by each working group.

Procedural

Working groups have been formed to examine the following issues: Dredging and related issues, electronic navigation systems, AtoN knockdowns, impact of passing vessels on moored ships, boater education issues, facilitating deep draft movements and mooring infrastructure. Not all working groups will provide a report at this session. Further, working group reports may not necessarily include discussions on all issues within the particular working group's area of responsibility. All meetings are open to the public. Please note that the meetings may adjourn early if all business is finished. Members of the public may make presentations, oral or written, at either meeting. Requests to make oral presentations or distribute written materials at the full HOGANSAC meeting should reach the Coast Guard five (5) working days before that meeting. Requests to have written materials distributed to each member of the full committee in advance of their meeting should reach the Coast Guard at least ten (10) working days before the full HOGANSAC meeting and should include fifteen (15) copies of the materials.

Information on Services for the Handicapped

For information on facilities or services for the handicapped or to request special assistance at the meetings, contact the Executive Director, Executive Secretary, or Assistant to the Executive Secretary as soon as possible.

Dated: January 27, 2006.

R.F. Duncan,

Rear Admiral, U.S. Coast Guard, Commander, Eighth Coast Guard District.

[FR Doc. 06–1276 Filed 2–7–06; 3:58 pm]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2006–23862]

Maritime Security Directive (MARSEC Directive) 104–6; Guidelines for U.S. Vessels Operating in High Risk Waters

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability.

SUMMARY: The Coast Guard announces the availability of MARSEC Directive 104–06. This MARSEC Directive provides guidelines for U.S. vessels operating in high risk waters. Information within this MARSEC