Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR Part 225) to engage *de novo*, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than February 12, 1999.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63102-2034:

1. Great Southern Bancorp, Inc., Springfield, Missouri; to acquire Guaranty Federal Bancshares, Inc., Springfield, Missouri, and thereby indirectly acquire Guaranty Federal Savings Bank, Springfield, Missouri, and thereby engage in the activity of operation of a savings association, pursuant to § 225.28(b)(4)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, January 14, 1999.

Robert deV. Frierson,

Associate Secretary of the Board.

[FR Doc. 99–1318 Filed 1–20–99; 8:45 am]

BILLING CODE 6210–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98P–0504]

Performance Standard for Vibrio Vulnificus; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has received a petition from the Center for Science in the Public Interest (CSPI) requesting that the agency establish a performance standard of ''nondetectable'' for the marine bacterium *Vibrio vulnificus* in raw molluscan shellfish harvested from waters that have been linked to illnesses from this organism. FDA is requesting information and views from the general public on CSPI's request and on several specific questions relating to the petition.

DATES: Submit written comments by April 21, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Patricia S. Schwartz, Center for Food Safety and Applied Nutrition (HFS–401), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3133.

SUPPLEMENTARY INFORMATION:

I. Background

V. vulnificus is a marine bacterium that can cause infection in humans as a result of contact through cuts or wounds and consumption of food containing the organism. The association of foodborne illness with *V. vulnificus* is relatively recent; the first reported cases occurred in the 1970's. To date, the food almost exclusively associated with illness from *V. vulnificus* is raw oysters harvested from States bordering on the Gulf of Mexico. However, the bacterium is also found in marine waters and in shellfish outside the Gulf region, although raw oysters from waters outside the Gulf region have not been definitively implicated in any cases of illness.

While *V. vulnificus* can infrequently cause gastroenteritis in healthy individuals, it can cause much more serious, sometimes deadly, septicemia in certain compromised individuals. The conditions that FDA believes put consumers at risk for septicemia from *V. vulnificus* include alcoholic liver disease, diabetes, hemochromatosis, chronic hepatitis B and C, and depressed immune system function. However, the majority of cases of septicemia have occurred in consumers with alcoholic liver disease. FDA estimates that the at-risk population in the United States falls within a range of 12 to 30 million. The number of septicemia cases reported from *V. vulnificus* each year range from a low of 9 in 1990 and 1991 to a high of 33 in 1996. Septicemia in medically compromised individuals has proven fatal in about 50 percent of reported cases. The agency's policy since 1993 has been that at-risk individuals should only consume molluscan shellfish that have been adequately cooked, as thorough cooking kills *V. vulnificus*.

FDA is supporting ongoing research directed toward answering several questions about *V. vulnificus*, including research: (1) To identify the characteristics of those strains of *V. vulnificus* that are pathogenic to humans, (2) to describe the effect of environmental conditions on the occurrence of these strains in water and in shellfish, (3) to determine whether there is an infectious dose or doses of the organism in susceptible humans, (4) to determine whether there are other factors or conditions that may put consumers at risk of septicemia; and (5) research on other matters. To date, FDA has cosponsored two national scientific workshops on *V. vulnificus* to determine what is known and what needs to be learned about this organism.

In addition, since 1993, the agency has expended considerable effort on education directed toward at-risk populations to warn them to avoid raw shellfish. Recently, the agency has supported point-of-purchase advisories directed toward at-risk individuals.

FDA has also worked with the Interstate Shellfish Sanitation Conference (ISSC), a cooperative entity (whose members include FDA, the States, and the shellfish industry) dedicated to the production of safe and sanitary molluscan shellfish, to address issues related to *V. vulnificus*. The agency participated with the ISSC in developing the post-harvest refrigeration requirements that were established by the ISSC for *V. vulnificus* in oysters. Together with the ISSC, FDA is currently studying the levels of these organisms in oysters to which consumers are exposed at retail.

FDA recognizes that innovative post-harvest technologies may also reduce or eliminate *V. vulnificus* from raw oysters. To foster this approach, the agency has provided labeling advice to a company that is marketing oysters that have been subject to a post-harvest treatment involving low temperature pasteurization (see the following paragraphs). The agency hopes that companies pursuing other potential post-harvest technologies will also seek FDA's labeling assistance.

II. The Citizen's Petition

On June 29, 1998, CSPI filed a citizen petition that requests that FDA issue regulations under the Federal Food, Drug, and Cosmetic Act or Public Health Service Act requiring nondetectable levels of *V. vulnificus* in raw molluscan shellfish harvested from waters that have been linked to illnesses or deaths

from this bacterium. *V. vulnificus* may be detected in virtually all oysters from such waters, at least during warm weather months. Thus, the practical effect of mandating a performance standard of ''nondetectable'' would be to impose post-harvest treatment requirements on all oysters from these waters.

The petition cites one such post-harvest treatment, that of the AmeriPure Co., which involves a mild heat treatment of in-shell oysters that is capable of killing *V. vulnificus*. FDA has reviewed data submitted by the AmeriPure Co. and those data do indicate that its process is capable of reducing *V. vulnificus* in oysters to nondetectable levels.

III. Request for Information and Views

Under FDA's administrative regulations (21 CFR 10.30(h)(3)), the agency, when reviewing a petition, may employ various procedures, including publishing a **Federal Register** notice asking for information and views. Accordingly, FDA is hereby soliciting comment on the issues raised by the CSPI petition. However, FDA is especially interested in comments, with supporting data where appropriate, on the following questions:

1. Is the AmeriPure Co. technology readily employable by the shellfish industry; if not, what barriers exist, and what steps could be taken to reduce or eliminate those barriers?

2. Other than the AmeriPure Co. process, what technologies, both present and anticipated, could significantly reduce the number of *V. vulnificus* in oysters while retaining the sensory qualities of a raw oyster? What is known about the ability of such technologies to reduce the number of *V. vulnificus* to nondetectable levels?

3. How reliable are such technologies? May they practically be required for an entire industry or a significant portion of that industry?

4. Would a performance standard have to be as low as ''nondetectable?'' Do data exist that would permit the setting of a performance standard above ''nondetectable?'' If so, at what level? Should the fact that *V. vulnificus* is found at low levels (less than 100 Most Probable Number/gram) in oysters in months (January and February) in which there have been no reported illnesses be taken into account when establishing a performance standard or level?

5. Should a performance standard apply to all raw molluscan shellfish or only to oysters?

6. What would be the quantifiable and nonquantifiable costs of a performance standard? Who would bear the costs? What would be the effect on costs, and the distribution of costs, if there was only one, patented process that could be used to meet the performance standard? What would the effect on costs be if a standard of ''nondetectable'' were put in place for all pathogens or for all raw molluscan shellfish?

7. What would be the quantifiable and nonquantifiable benefits of a performance standard? Who would enjoy the benefits?

8. Another marine pathogen, *V. parahaemolyticus*, has caused over 700 reported cases of illness (gastroenteritis) during 1997 and 1998. There has been one death reported to the Centers for Disease Control and Prevention and several hospitalizations. Illnesses from *V. parahaemolyticus* have occurred from oysters harvested outside of the Gulf of Mexico region.

Should a performance standard apply only to *V. vulnificus* or should it apply to other Vibrio species that post-harvest treatment might be able to reduce to nondetectable levels?

IV. Request for Comments

Interested persons may, on or before April 21, 1999, submit to the Dockets Management Branch (address above) written comments regarding this notice. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 1999.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 99–1361 Filed 1–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1265]

Federal/State Memorandum of Understanding on Interstate Distribution of Compounded Drug Products; Draft; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft standard memorandum of understanding (MOU) that States may enter into with FDA. The draft standard MOU entitled ''Memorandum of Understanding on Interstate Distribution of Compounded Drug Products'' describes the responsibilities of the States and FDA in investigating and responding to complaints related to compounded drug products distributed interstate and addresses the interstate distribution of inordinate amounts of compounded drug products. FDA has developed this MOU in consultation with the National Association of Boards of Pharmacy (NABP), under provisions of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act).

DATES: Written comments may be submitted on the draft standard MOU by March 22, 1999.

ADDRESSES: Copies of the draft standard MOU are available on the Internet at ''http://www.fda.gov/cder/pharmcomp/default.htm''. Submit written requests for single copies of the draft standard MOU entitled ''Memorandum of Understanding on Interstate Distribution of Compounded Drug Products'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Requests and comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Brian L. Pendleton, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5649.

SUPPLEMENTARY INFORMATION: On November 21, 1997, the President signed into law the Modernization Act (Pub. L. 105–115). Section 127 of the Modernization Act added section 503A to the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 353a), which exempts compounded drug products from the requirements in sections 501(a)(2)(B) (current good manufacturing practices), 502(f)(1) (adequate directions for use), and 505 (new drug provisions) of the act (21 U.S.C. 351(a)(2)(B), 352(f)(1), and 355), provided that the compounding is conducted in accordance with, and the drug products meet, the requirements in section 503A of the act.

Section 503A(b)(3)(B)(i) and (b)(3)(B)(ii) of the act states that a