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

compounded drug product may be eligible for the previously noted exemptions if it is compounded under either of two conditions. These conditions are as follows: (1) The State in which the drug is compounded has entered into an MOU with FDA ''which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State''; or (2) the State in which the drug is compounded has not entered into such an MOU and a licensed pharmacist, pharmacy, or physician ''distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.'' Section 503A(b)(3)(B) of the act directs FDA to develop, in consultation with the NABP, a standard MOU for use by the States in complying with section 503A(b)(3)(B)(i) of the act.

FDA consulted with the NABP concerning this standard MOU, and the agency is now making available for public comment a draft standard MOU regarding the interstate distribution of compounded drug products. The draft standard MOU sets forth the responsibilities of State agencies and FDA with respect to the following: (1) Investigating and responding to complaints relating to compounded drug products distributed outside of a State, and (2) responding to the distribution of inordinate amounts of compounded drug products in interstate commerce.

FDA invites comments from interested persons on the draft standard MOU on the interstate distribution of compounded drug products. The agency is providing a 60-day comment period and is establishing a docket for the receipt of comments. As stated in its guidance for industry entitled ''Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act'' (see 63 FR 64723, November 23, 1998), after considering any comments on the draft standard MOU submitted to this docket, FDA will finalize the standard MOU and make it available for signature by individual State agencies. Until at least 90 days after the standard MOU is finalized and made available to the States for their consideration and signature, the agency intends to exercise its enforcement discretion and normally will not take regulatory action regarding the requirement in section 503A(b)(3)(B)(ii) of the act, which states that a licensed pharmacist, pharmacy, or physician may not distribute or cause to be distributed in interstate commerce compounded drug products constituting more than 5 percent of the total prescription orders dispensed or distributed.

Interested persons may, on or before March 22, 1999, submit to the Dockets Management Branch (address above) written comments on the draft standard MOU. 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. The draft standard MOU and 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. 99–1366 Filed 1–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–1169]

Draft Guidance for Industry on Content and Format for Geriatric Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Content and Format for Geriatric Labeling.'' FDA established the ''Geriatric use'' subsection in the labeling for human prescription drug products in a final rule. The Geriatric use subsection includes biological drug products in order to provide for the inclusion of information pertinent to the appropriate use of drugs in the elderly (persons aged 65 and over). This draft guidance is intended to provide industry with information on submitting geriatric labeling for human prescription drug and biological products, including who should submit revised labeling, the implementation schedule, a description of the regulation and optional standard language in proposed labeling, the content and format for geriatric labeling, and the applicability of user fees to geriatric labeling supplements.

DATES: Written comments may be submitted on the draft guidance by March 22, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''. Submit written requests for single copies of ''Content and Format for Geriatric Labeling'' to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Office of Communication, Training and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Diana M. Hernandez, Center for Drug Evaluation and Research (HFD–006), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–6779; or

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), 1401 Rockville Pike, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a draft guidance for industry entitled ''Content and Format for Geriatric Labeling.'' This draft guidance has been developed in response to a final rule that published in the **Federal Register** of August 27, 1997 (62 FR 45313), establishing, in the ''Precautions'' section of prescription drug labeling, a subsection on the use of drugs in elderly or geriatric patients (aged 65 years or over) (§ 201.57(f)(10) (21 CFR 201.57(f)(10))). The geriatric labeling regulation recognizes the special concerns associated with the geriatric use of prescription drugs and acknowledges the need to communicate important information so that drugs can be used safely and effectively in older patients. The medical community has become increasingly aware that prescription drugs can produce effects in the elderly that are significantly different from those produced in younger patients. Geriatric labeling information is of increasing importance because of the growing proportion of the population that is over 65 years of age