application must also demonstrate that the ISSC has the financial and other resources required for this project.

3. The application must specify the approach that the ISSC will use to solicit proposals for *V. vulnificus* research.

4. The ISSC application must explain how the ISSC will monitor the progress of selected research projects, and how it will keep FDA informed of any significant advances in the understanding of or control of *V. vulnificus*.

In addition, FDA will determine whether the estimated cost of the project is reasonable. The application must include a detailed budget that shows: (1) Anticipated costs for personnel, travel, communications and postage, equipment, and supplies; and (2) the sources of funds to meet those needs.

VII. Reporting Requirement

All terms and conditions of the current award shall remain in full force and effect for the supplemental award.

As a result of this supplemental award, annual project progress reports must also include the following:

1. Listing of research projects funded.
2. Specific purpose of each project.
3. Cost of each project.
4. Anticipated completion and milestone dates for each project.
5. Year-to-date results/scientific findings/public health findings of each project.
6. Potential *V. vulnificus* control measures/strategies suggested by research efforts.

VIII. Mechanism of Support

Support for this project will be in the form of a supplement to FDA's cooperative agreement with the ISSC. This agreement will be subject to all policies and requirements that govern the research grant programs of the PHS, including provisions of 42 CFR part 52 and 45 CFR part 74.

Dated: September 10, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–23669 Filed 9–13–96; 8:45 am]

BILLING CODE 4160–01–F

[Docket No. 96N–0309]

Promotion of FDA-Regulated Medical Products on the Internet; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting to discuss issues related to the promotion of FDA-regulated medical products on the Internet. FDA is seeking participation in the public meeting and written comments from all interested parties, including, but not limited to, consumers, patient groups, information vendors, manufacturers of FDA-regulated medical products, and health care professionals. This meeting and the written comments are intended to help guide FDA in making policy decisions on the promotion of biologics, human and animal drugs, and medical devices on the Internet and the World Wide Web (the Web).

DATES: The public meeting will be held on Wednesday, October 16, 1996, from 8:30 a.m. to 5 p.m. and on Thursday, October 17, 1996, from 8:30 a.m. to 3 p.m. Registration for persons who wish to actively participate in the discussion groups is required by October 4, 1996. Registration is not required for persons who wish to be in the audience. Written comments will be accepted until December 16, 1996.

ADDRESSES: The public meeting will be held at the Quality Hotel, 8727 Colesville Rd., Silver Spring, MD. Individuals who wish to actively participate in the public meeting should mail, fax, or e-mail their registration information to Fay Fink (address below). There is no registration fee for this meeting, but registration is required for individuals who wish to actively participate in the group discussions. Seating for each discussion group is limited to 15 persons, on a first-come, first-serve basis. Information about the public meeting is also available on FDA's website at http://www.fda.gov. Submit written comments on the questions to the Dockets Management Branch (DMB) (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. After the meeting, a transcript will be available at DMB (address above) between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

Regarding registration: Fay Fink, Office of Policy (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3360, FAX 301–594–6777, e-mail: FFink@bangate.fda.gov.

Regarding this notice: Ilisa B.G. Bernstein, Office of Policy (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380, e-mail: IBernste@bangate.fda.gov; or Melissa M. Moncavage, Center for Drug Evaluation and Research (HFD–40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2828, e-mail: moncavage@cder.fda.gov or Byron L. Tart, Center for Devices and Radiological Health (HFZ–302), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–4639, e-mail: bxt@fdadr.cdrh.fda.gov.

SUPPLEMENTARY INFORMATION:

I. Background

With the recent dramatic increases in the number of users of the Internet, including the Web, companies, including manufacturers and distributors of products regulated by FDA, are looking at the Internet as a medium for disseminating information about their products. FDA is evaluating how the statutory provisions, regulations, and policies concerning advertising and labeling should be applied to product-related information on the Internet and whether any additional regulations, policies, or guidances are needed. Although the agency believes that many issues can be addressed through existing FDA regulations, special characteristics of the Internet may require the agency to provide guidance to the industry on how the regulations should be applied.

The Internet is a global network of computers. The most widely used portion of the Internet is the Web. The Web permits the display of multimedia documents and objects, such as plain text, searchable indices, images, sounds, movies, and fill-in forms. Web pages can be linked to other sites on the Web using ''hypertext,'' which allows the user to jump to any other information page that is linked to the Web. The Web is where most promotion of FDA-regulated products is located on the Internet. In addressing promotional issues in this notice, FDA will use the broader term, Internet, which includes the Web.

Since late 1995, FDA has been gathering information about the Internet and its utility to promote FDA-regulated products. This is in an effort to facilitate the development of guidance to the industry on the promotion of regulated products on the Internet. As part of its fact finding process, FDA has been meeting with companies, third party providers, and other groups, to gain a better understanding of the nature of, and the technical aspects to, promotion on the Internet. FDA appreciates the time and effort that these individuals, companies, and associations have

invested in assisting the agency to understand the Internet.

In this notice, FDA is announcing two actions to get broader input from the public on issues related to the promotion of FDA-regulated products over the Internet. First, FDA is announcing a public meeting to discuss these issues. Second, the agency is presenting questions for public comment to assist in the policy development process. Based on discussions with the public and inquiries from regulated industry, the agency has identified several issues related to promotion on the Internet that need to be addressed. This list of issues is by no means exhaustive, and the agency is open to suggestions for additional issues to be addressed.

II. Public Meeting

The public meeting is being held to discuss issues related to the promotion of FDA-regulated products over the Internet. The objective of the meeting is for the agency to receive broad public input and to hear various points of view and opinions on Internet issues from a dialogue among interested persons. The agency believes that a discussion group format would best further this goal. Therefore, the 2-day meeting will be conducted as a consecutive series of five discussion groups, led by a moderator. (Only one discussion group will be going on at a time.) A panel of FDA officials will listen to each discussion group and ask the group participants probing questions at the end of each discussion period. The audience will then have an opportunity to ask questions and comment on the topics.

Those persons interested in actively participating in the group discussions should mail, fax, or e-mail their registration to Fay Fink (address above) including name, affiliation, address, phone number, fax number, e-mail address, and the discussion group(s) in which you would like to participate, in rank order. There is no registration fee for this meeting, but registration is required for individuals who wish to actively participate in the group discussions. Seating for each discussion group is limited to 15 persons, on a first-come, first-serve basis. FDA will attempt to balance the representation of constituents on the discussion groups and will attempt to give all interested parties an opportunity to participate in at least one group. The agency will maintain a waiting list in the event of cancellations or no-shows. The agency reserves the right to limit the number of participants from the same organization or company in a discussion group. The agency invites all other interested persons who wish to attend the meeting to sit in the audience during these discussion sessions. Registration is not required for persons who wish to be in the audience. As discussed earlier, there will be opportunities for persons in the audience to ask questions and comment on the various topics discussed.

Prior to the meeting, the agency will distribute a list of questions that will be presented to each discussion group. The list of questions will be placed on file in the public docket (docket number found in brackets in the heading of this document) and will be available on the FDA website with the other information about this meeting.

As stated previously, each discussion group will address a particular topic. The list of topics to be discussed during the 2-day meeting are as follows:

Wednesday, October 16, 1996:

Discussion Group 1—Investigational Product Information

Discussion Group 2—Chatrooms and Newsgroups

Discussion Group 3—Additional Regulatory Issues

Thursday, October 17, 1996:

Discussion Group 4—Website Links

Discussion Group 5—International Issues

Discussion Group 3 (Additional Regulatory Issues) will discuss additional issues that were not covered in the other discussion groups. If individuals have regulatory issues they would like addressed, which are not discussed in other sessions, the agency would like to include those topics in the discussion under Group 3. The agency invites interested persons to submit suggestions for discussion by this group by October 4, 1996. The agency will consider these suggestions and prepare a list of selected topics for discussion prior to the meeting. That list will be available in the public docket and on the FDA website by October 9, 1996.

III. Internet Questions

As described above, a number of questions have arisen regarding the application of the advertising and labeling provisions, regulations, and policies to promotion on the Internet. This section will briefly discuss the issues the agency has identified as most frequently raised by regulated companies and other interested parties. It should be noted that although these questions may raise a particular issue, that does not necessarily mean that the agency will issue guidance or a regulation on the particular issue.

A. Presentation of Product Information

The Federal Food, Drug, and Cosmetic Act (the act) and its implementing regulations define the conditions under which human and animal drugs, biologics, and medical devices shall be advertised or otherwise promoted (e.g., package insert, brief summary, brief statement). For prescription human and animal drugs and biologics, full product information (approved labeling), including indications for use, dosing, warnings, adverse affects, precautions, etc., shall be included with the dissemination of any labeling, as defined in section 201(m) of the act (21 U.S.C. 321(m)). (See section 502(f)(1) of the act (21 U.S.C. 352(f)(1)) and 21 CFR 201.100(d).) For prescription human drugs, biological products, and prescription animal drugs, advertisements must contain a true statement of information in brief summary relating to side effects, contraindications, and effectiveness. (See section 502(n) of the act and 21 CFR 202.1(e).) For medical devices, any labeling as defined in section 201(m) of the act, including promotional labeling for prescription devices, must contain adequate information that includes indications for use, effects, routes, methods, and frequency of administration and any relevant hazards, contraindications, side effects, and precautions. (See 21 CFR 801.109.) Additionally, for restricted medical devices, under section 502(r) of the act, advertisements shall include a ''brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.''

Several companies have inquired about the application of the regulations and statutory provisions described above, as they relate to product information on the Internet. Because the agency has received inquiries about this issue, FDA is interested in comments addressing the following questions:

1. How should product information be presented to ensure that Internet users will know that the product information is available and where it is available?

2. Does it matter where product information is located on the website? If so, where should it be located?

3. How can product information be clearly distinguished from other information on the Internet (e.g., disclosure statements)?

4. Under 21 CFR 202.1(e)(5)(ii), prescription drug advertisements are required to present a ''* * * fair balance between information relating to side effects and contraindications and information relating to effectiveness of the drug * * *.'' Traditionally, the agency has interpreted this regulation such that the copy of the advertisement and the format of the information

should be ''fairly balanced.'' How should product information be presented on the Internet to ensure that the user has access to a balanced presentation of both side effects and contraindications and information relating to effectiveness? For example, should ''fair balance'' be considered in the presentation of information on every screen? In every advertisement or promotional piece? Or on the entire website?

B. Direct-to-Consumer Promotion

Most product information on the Internet is written in technical language directed to health care professionals. FDA recognizes that many Internet users may not have the technical background to fully understand the language typically used in prescription drug, biological product, and medical device promotion.

In the Federal Register of May 14, 1996 (61 FR 24314), FDA published a notice seeking public comment on several issues related to direct-to-consumer promotion, including whether certain FDA-approved patient labeling, written in language easier for consumers to understand, should be considered as adequate to fulfill the brief summary requirement for consumer-directed prescription drug and biological product advertisements. FDA will use the comments received in response to the May 14, 1996, Federal Register notice, in its consideration of how product information should be presented on the Internet. Additionally, FDA has the following questions regarding Internet promotion directed to consumers:

1. Is it necessary to distinguish between promotion directed to health professionals and consumers on the Internet?

2. If yes to question 1., directly above, how should websites clearly make the distinction between professional-directed and consumer-directed promotion?

C. Links Between Websites

The Internet allows users to move easily between websites that provide information on many related topics. Websites can offer the user an opportunity to click on a topic heading (a word, word string, button, or icon) from a list of headings and be linked automatically to another location within the same website or to the website of another organization. Thus, it is possible for FDA-regulated industry sponsored websites to provide links to other sites with information about diseases, products, etc., some of which contain information about unapproved uses of approved products. Under the act, companies are prohibited from promoting approved human and animal drugs, biological products, and medical devices for unapproved uses. FDA has the following questions regarding links between websites:

1. Should links from websites, posted or sponsored by a regulated company and containing information about FDA-regulated products be permitted? Why or why not?

2. If yes to question 1., directly above, what parameters, if any, should be established for links from such websites to other websites, without violating the act.

3. On some websites, before leaving the website to link to another website, the user is automatically presented with a screen that indicates that the user is leaving the website to go to another one. Is there any benefit to this type of information?

D. Investigational Product Information

Several companies that market FDA-regulated medical products have inquired about the extent to which information regarding investigational products or investigational uses of products can be placed on their website. Currently, FDA regulations prohibit representing ''* * * in a promotional context that an investigational new drug is safe or effective for the purposes for which it is under investigation * * *'' and prohibits the ''* * * commercialization of the drug before it is approved for commercial distribution.'' (See 21 CFR 312.7(a).) A similar regulation applies to investigational devices. (See 21 CFR 812.7.) Many companies have placed on their website information intended for stockholders or potential stockholders, which often contain information about products or uses under investigation. In some cases, however, it is difficult for the Internet user to distinguish whether the presentation of this information is intended for economic or promotional purposes. The agency recognizes that information about investigational products and uses can be useful in the context of scientific exchange. FDA has the following questions regarding investigational product information:

To what extent should information about investigational products or investigational uses be presented on a sponsoring company's website? Is there a way to distinguish between the presentation of this information for economic, educational, or promotional purposes?

E. Chatrooms and Newsgroups

Chatrooms are Internet locations where users can have ''real time'' conversations with other users. Newsgroups are Internet locations where users can post messages for other users to read and/or respond to other posted messages. The information discussed in chatrooms and posted in newsgroups is often focused on a specific issue or interest. FDA has the following questions on chatrooms and newsgroups:

1. Do FDA-regulated companies maintain or sponsor chatrooms or newsgroups about their products, either focussed specifically on one product or on disease states or conditions? If so, what are the reasons for doing so and what is the experience to date? If not, what are the reasons for not doing so? What is the experience to date with respect to the dissemination of false or misleading information about FDA-regulated products by noncompany users of the Internet?

2. Should parameters be established for company participation in, or sponsorship of, chatrooms or newsgroups that discuss the company's product(s)? If so, what should they be?

3. Some companies have expressed a desire to correct, what is in their belief, misconceptions or misinformation about unapproved uses of their products, which may be presented in chatrooms and newsgroups. Some of these companies have stated that they have not corrected the information in the belief that they could be considered promoting the unapproved use. Should such information be regarded as violative promotion? Are there any parameters or criteria that could be used to determine the appropriateness or scope of such corrections.

F. International Issues

FDA has heard from some multinational pharmaceutical, biologic, and device companies that wish to centralize their Internet product information dissemination from one server within the United States. Under the act and current regulations, however, companies may not advertise or otherwise promote their approved or unapproved products within the United States for uses that are not approved in this country. A company's products may be approved in other countries, but not in the United States, or may be approved in the United States, but for different uses in other countries. Consequently, companies could be considered promoting unapproved products or uses in the United States by disseminating information about products approved in foreign countries to U.S. citizens. FDA has the following questions on international issues:

1. How could promotion of products manufactured or distributed by multinational companies be presented on the Internet without violating the act and regulations?

2. What factors should FDA consider in determining whether a company is attempting to promote a product within the United States, which is approved for a use in another country, but not so approved in the United States?

3. What policies and regulations have other countries established or are considering with respect to the dissemination of information about medical products over the Internet?

FDA welcomes comments on all of the issues described above.

Dated: September 10, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–23616 Filed 9–13–96; 8:45 am]

BILLING CODE 4160–01–F

Indian Health Service

Submission for OMB Review; Comment Request, Indian Health Service, Hospital, Dental and Other Contract Health Service Reports

SUMMARY: Under the provisions of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection activity was previously published in the Federal Register (61 FR 17903) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow 30 days for public comments to be submitted to the OMB. The IHS may not conduct or sponsor, and the respondent is not required to respond to any information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

PROPOSED COLLECTION: *Title:* Indian Health Service Contract Health Service Reports. *Type of Information Collection Request:* A 1-year reinstatement with change of previously approved information collection 0917–0002, Indian Health Service contract Health Service Reports'' *Need and Use of Information Collection:* These information collection forms are completed by IHS CHS Providers and used to certify that the health care services requested and authorized by the IHS have been performed by the CHS Provider(s), process payments for health care services performed by such providers; and serve as a legal document for health and medical care authorized by the IHS and rendered by providers under contract with the IHS. The burden estimate for this information collection activity follows:

Information collection activity	No. of respondents	Responses per respondent	Average burden per response (hours) [1]
IHS–43–1A	429	148	0.167 (10 mins).
IHS–57–1A	403	22	0.418 (25 mins).
IHS–64–1A	5,768	32	0.167 (10 mins).
New form: IHS–843–1A	6,600	41	0.05 (3 mins).
Inpatient Discharge Summary [2]	63,492	1	0.05 (3 mins).

[1] Provided in decimal unit values of an hour and in actual minutes.

[2] The inpatient discharge summary was overlooked as an information collection activity in prior approval requests and is added accordingly. In the **Federal Register** notice (61 FR 17903), the number of respondents and the average burden per response for the IDS were overstated. Both have been adjusted.

REQUEST FOR COMMENTS: Written comments and suggestions from the public and affected agencies are invited on one or more of the following points: (a) Whether the information collection activity is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used to determine the estimate; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology.

DIRECT COMMENTS TO OMB: Written comments and suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS. To request more information on the proposed information collection activity or to obtain a copy of the data collection plan(s) and/or instrument(s), contact: Mr. Lance Hodahkwen, Sr., M.P.H., IHS Reports Clearance Officer, 12300 Twinbrook Plaza, Suite 450, Rockville, MD 20857; or call non-toll-free number (301) 443–0461; or send via facsimile to (301) 443–1522 or Internet (include your address) to: Lhodahkw@ihs.ssw.dhhs.gov.

COMMENTS DUE DATE: Comments regarding this information collection activity are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 28, 1996.

Michael H. Trujillo,

Assistant Surgeon General, Director.

[FR Doc. 96–23551 Filed 9–13–96; 8:45 am]

BILLING CODE 4160–16–M

Office of Inspector General

Program Exclusions: August 1996

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of August 1996, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusion is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, Maternal and Child Health Services Block Grant and Block Grants to States for Social Services programs. In addition, no program payment is made to any business or facility, e.g., a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an