

DMPB

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99N-0053]

**Announcement of a Pilot Customer Satisfaction Survey: Medical Device Inspection Evaluation**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing a 1-year pilot of a customer satisfaction survey entitled "Medical Device Inspection Evaluation." The purpose of the evaluation is to provide a means whereby the medical device industry can provide feedback in an anonymous way to FDA's Office of Regulatory Affairs (ORA) regarding the medical device inspectional process. ORA intends to utilize a third party to collect the evaluations and trend the data submitted.

**DATES:** Written comments may be submitted at any time between March 1, 1999, through February 28, 2000.

**ADDRESSEES:** 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:** Denise D. Dion, Office of Regulatory Affairs, Division of Emergency and Investigational Operations (HFC-130), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5645, e-mail "ddion@ora.fda.gov".

**SUPPLEMENTARY INFORMATION:** The Office of Management and Budget (OMB) has granted approval for this evaluation as a customer satisfaction survey. The evaluation is a followup to FDA/ORA's successful medical device industry initiatives, which included preannounced inspections, FDA 483 annotations, and postinspection notification letters. The Medical Device Industry Initiative Grassroots Taskforce, which includes members from industry and industry trade

groups from across the nation as well as from FDA/ORR and FDA/Center for Devices and Radiological Health, is responsible for the design and development of this evaluation tool. The University of California-Irvine (UCI) Center for Statistical Consulting, Irvine, CA, is the third party that will collect and collate the evaluation forms and data. The data trends and findings will be made publicly available and will be shared with industry. The evaluation will be piloted for medical device preapproval, quality system/good manufacturing practices, and other related inspections.

The evaluation forms will contain preprinted information completed by the investigator regarding the name of the firm inspected, date of inspection, whether an FDA 483 was issued, the name of the investigator(s), the applicable FDA District Office and the reason for the inspection. The form will be accompanied by a preaddressed stamped envelope that is to be used to return the form to the UCI Center for Statistical Consulting (UCI). FDA expects the firm official with the most knowledge of the inspection to complete the industry survey portion of the evaluation as soon as possible after the inspection has ended. UCI will report the results by FDA District, FDA Region and nationwide.

The purpose of including investigator and firm identifiers on the evaluation is to assist UCI in obtaining clarifying information if needed and to determine the number of responses received versus the number of inspections conducted. FDA/ORR intends to share FDA's inspectional accomplishments (numbers) with UCI to help facilitate this determination of response rate. Neither the firm nor investigator identifier information will be entered into the data base or shared with FDA or industry.

The information collection provisions in this notice have been approved under OMB control number 0910-0360. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

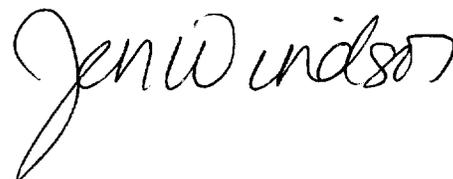
Interested persons may, at any time between March 1, 1999, through February 28, 2000, submit written comments to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to

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.

**[INSERT GRAPHIC]**

Dated: January 21, 1999  
January 21, 1999

**CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL**



William K. Hubbard  
Associate Commissioner  
for Policy Coordination

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

**BILLING CODE 4160-01-F**



Q-3 Was it necessary to reschedule the proposed start of the inspection?

- 1 YES
- 2 NO

(If yes) Was the impact on your business

- 1 HELPFUL
- 2 NEUTRAL
- 3 DISRUPTIVE

**The next set of questions asks about things that may have happened during the inspection.**

Q-4 Was it necessary to interrupt the inspection for more than two working days?

- 1 YES
- 2 NO

(If yes) Was the interruption requested by

- 1 FDA
- 2 YOUR COMPANY

Characterize the impact of the interruption on your company

- 1 HELPFUL
- 2 NEUTRAL
- 3 DISRUPTIVE

Q-5 Were you able to have **all** the right personnel available during the inspection?

- 1 YES
- 2 NO → PLEASE EXPLAIN: \_\_\_\_\_

Q-6 Was your company able to meet **all** the needs of the investigator(s) for records availability?

- 1 YES
- 2 NO → PLEASE EXPLAIN: \_\_\_\_\_

Q-7 During the process of the inspection was your firm always notified daily of the investigator(s) observations?

- 1 YES
- 2 NO → PLEASE EXPLAIN: \_\_\_\_\_

Q-8 Did the investigator(s) provide any helpful information or suggestions?

- 1 YES
- 2 NO

**The following questions pertain to the outcome of the inspection.**

Q-9 Was an FDA 483 issued at the close of the inspection?

- 1 YES
- 2 NO → SKIP TO Q-18 ON THE BACK PAGE

Q-10 Were there any corrective actions taken or promised by your company during the process of the inspection?  
(CIRCLE **ALL** THAT APPLY)

- 1 YES, TAKEN
- 2 YES, PROMISED
- 3 NO, NEITHER → SKIP TO Q-14 ON THE NEXT PAGE

Q-11 Were there any corrective actions taken that were not verified by the FDA inspectors (i.e., not verified by the FDA)?

- 1 YES \_\_\_\_\_
- 2 NO \_\_\_\_\_
- 3 N/A. NO CORRECTIVE ACTIONS TAKEN \_\_\_\_\_

Please list the corrective actions taken which you believe could have been verified by the FDA inspectors) but were not: \_\_\_\_\_

Q-12 Have you already, or do you plan to fulfill any promised actions?

- 1 YES \_\_\_\_\_
- 2 NO \_\_\_\_\_
- 3 N/A. NO CORRECTIVE ACTIONS PROMISED \_\_\_\_\_

(If no) Have you advised the FDA of any changes in plans or delays? \_\_\_\_\_

- 1 YES \_\_\_\_\_
- 2 NO \_\_\_\_\_

Q-13 Were the promised or taken corrective actions appropriately annotated on the FDA 483?

- 1 YES. ALL WERE \_\_\_\_\_
- 2 SOME WERE. SOME WERE NOT \_\_\_\_\_
- 3 NO. NONE WERE \_\_\_\_\_

Please list whatever actions you believe were not appropriately annotated on the FDA 483: \_\_\_\_\_

Q-14 Were there any inaccuracies on the FDA 483 other than those you may have described in Q-13 above?

- 1 YES \_\_\_\_\_
- 2 NO \_\_\_\_\_

(If yes) Were these inaccuracies on the FDA 483 corrected? \_\_\_\_\_

- 1 YES \_\_\_\_\_
- 2 NO → Please describe the situation(s): \_\_\_\_\_

\_\_\_\_\_

**The final set of questions asks your evaluation of the inspection and about your company's actions.**

Q-15 Were all of the observations on the FDA 483 understandable?

- 1 YES \_\_\_\_\_
- 2 NO → Please comment on what was not clear: \_\_\_\_\_

Q-16 Other than inaccuracies (noted in Q-14 above), were any of the observations on the FDA 483 inappropriate?

- 1 YES \_\_\_\_\_
- 2 NO \_\_\_\_\_

(If yes) Inappropriate items on the 483 were (CIRCLE ALL THAT APPLY):

- 1 INSIGNIFICANT OBSERVATIONS \_\_\_\_\_
- 2 DIFFERENCE OF INTERPRETATION \_\_\_\_\_
- 3 OTHER → Please explain: \_\_\_\_\_

Q-17 Do you plan to respond to the FDA 483 observations in writing?

- 1 YES
- 2 NO → Please Explain: \_\_\_\_\_

Q-18 How did this inspection process compare with past inspections?

- 1 THIS WAS BETTER → Please explain: \_\_\_\_\_
- 2 SAME
- 3 THIS WAS WORSE → Please explain: \_\_\_\_\_
- 4 NEVER BEEN INSPECTED BEFORE

Q-19 Was the highest level executive in your facility in attendance at the final discussion with management?

- 1 YES
- 2 NO

Q-20 Worldwide, what is the total number of people your company employs in its medical device division(s)?

\_\_\_\_\_ NUMBER OF PEOPLE

Finally, we ask that you provide contact information should we need clarification about any of your responses. This is for the use by The UCI Center for Statistical Consulting *only* and will *not* be released to the FDA, to any industry group, or to anyone else.

**Person Completing this Evaluation:**

**Name:** \_\_\_\_\_

**Title:** \_\_\_\_\_

**Telephone:** \_\_\_\_\_

**Fax:** \_\_\_\_\_

**We Invite Your Comments.** We would like your suggestions concerning how the FDA inspection process could be improved. In particular, we would appreciate information concerning specific questions. If your comment pertains to a particular question number, it would be helpful if you would note the question number.

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*Thank you very much for your help!*

**Please return completed questionnaire to:**

Anita Iannucci, Ph.D.  
 The UCI Center for Statistical Consulting  
 Social Science Plaza  
 University of California  
 Irvine, CA 92697-5105  
 (949) 824-1682 iannucci@uci.edu