SMG 2130.4

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

SAFETY AND OCCUPATIONAL HEALTH PROGRAMS

SAFETY AND OCCUPATIONAL HEALTH INSPECTIONS

Transmittal Number 88-89 -- Date: 07/11/1988

1. PURPOSE

To establish policy and designate responsibilities for an annual safety and occupational health inspection program for the Food and Drug Administration.

2. BACKGROUND

Federal, Department of Health and Human Services, and Public Health Service policy and FDA Staff Manual Guides require that all areas and operations of each workplace, including office operations, be inspected at least annually. This guide is designed to meet the requirement for inspections in FDA establishments.

3. REFERENCES

See references itemized in Staff Manual Guide 2130.1.

4. DEFINITIONS

Definitions found in Staff Manual Guide 2130.1 shall be applied to terminology referenced in this guide.

5. POLICY

It is the policy of the Food and Drug Administration that each organizational component of the FDA (Office of the Commissioner, Offices of the Associate Commissioners, Centers) conduct on internally managed safety and occupational health inspection of each establishment at least one time during each fiscal year.

6. RESPONSIBILITIES

In addition to those responsibilities noted below, see applicable responsibilities itemized in Staff Manual Guide 2130.1.

A. Heads of Offices of the Commissioner, Associate Commissioners, Centers.

1. Develop written internal policy and procedures to implement the FDA policy stated above. The procedures shall include the development and, at least, annual maintenance of a standard inspection checklist, approved in writing by the manager of the establishment to be inspected, which is adequate in scope and content to meet the responsibility placed with each Office/Center Head to provide safe and healthful places and conditions of employment. Checklists shall include those relevant topics found in the most recent Safety Evaluation check list utilized in the conduct of the FDA On-Site Management Review Program.

2. Conduct at least one inspection of each establishment each year in accordance with provisions of the Department of Labor's Occupational Safety and Health Administration, Departmental, PHS, and FDA policy.

3. Forward a copy of the inspection findings to the FDA Safety Office no later than 21 calendar days after the first day of the next fiscal year. Such findings should include any deficiencies previously identified, but which remain unresolved. Additionally, a plan to correct the identified deficiencies shall be forwarded with the findings.

4. Take action to address deficiencies found, to include elevating problems, which are beyond the control of local management to correct, to the next level of management for action; and providing interim corrective measures while long-term solutions are developed.

B. FDA Safety Office

1. Provide to the Heads of Offices of the Commissioner, Associate Commissioners and Centers a copy of the most current Safety Evaluation Checklist, utilized in the conduct of the Safety Evaluation portion of the FDA On-Site Management Review Program, for incorporation, as appropriate, into Office/Center annual inspection checklists.

2. Advise, on at least an annual basis, the Agency's Designated Safety and Health Official (Associate Commissioner for Management and

Operations) of the status of the Agency safety inspection program establish by this Guide.