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Elizabeth M. Duke,
Administrator.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

OIG Compliance Program Guidance for Pharmaceutical Manufacturers

AGENCY: Office of Inspector General
(OIG), HHS.

ACTION: Notice

SUMMARY: This **Federal Register** notice sets forth the recently issued Compliance Program Guidance for Pharmaceutical Manufacturers developed by the Office of Inspector General (OIG). Through this notice, the OIG is setting forth its general views on the value and fundamental principles of compliance programs for pharmaceutical manufacturers and the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Background

Compliance program guidance is a major initiative of the OIG in its effort to engage the health care community in preventing and reducing fraud and abuse in federal health care programs. The purpose of the compliance program guidance is to encourage the use of internal controls to efficiently monitor adherence to applicable statutes, regulations and program requirements. In the last several years, the OIG has developed and issued compliance program guidance directed at the following segments of the health care industry: the hospital industry; home health agencies; clinical laboratories; third-party medical billing companies; the durable medical equipment, prosthetics, orthotics and supply industry; Medicare+Choice organizations offering coordinated care plans; hospices; nursing facilities; individual and small group physician practices; and ambulance suppliers.

Copies of these compliance program guidances can be found on the OIG Web site at <http://oig.hhs.gov/fraud/complianceguidance.html>.

Developing the Compliance Program Guidance for Pharmaceutical Manufacturers

On June 11, 2001, the OIG published a solicitation notice seeking information and recommendations for developing compliance program guidance for the pharmaceutical industry (66 FR 31246). In response to that solicitation notice, the OIG received eight comments from various outside sources. We carefully considered those comments, as well as previous OIG publications, such as other compliance program guidances and Special Fraud Alerts. In addition, we have taken into account past and ongoing fraud investigations conducted by the OIG's Office of Investigations and the Department of Justice, and have consulted with the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration). In an effort to ensure that all parties had a reasonable opportunity to provide input into a final product, draft compliance program guidance for the pharmaceutical industry was published in the **Federal Register** on October 3, 2002 (67 FR 62057) for further comments and recommendations.

Elements for an Effective Compliance Program

This compliance program guidance for pharmaceutical manufacturers contains seven elements that have been widely recognized as fundamental to an effective compliance program:

- Implementing written policies and procedures;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and
- Responding promptly to detected problems and undertaking corrective action.

These elements are included in previous guidances issued by the OIG. As with previously issued guidances, this compliance program guidance represents the OIG's suggestions on how pharmaceutical manufacturers can establish internal controls to ensure adherence to applicable rules and program requirements. The contents of this guidance should not be viewed as mandatory or as an exclusive discussion of the advisable elements of a compliance program. The document is intended to present voluntary guidance

to the industry and not to represent binding standards for pharmaceutical manufacturers.

Office of Inspector General's Compliance Program Guidance for Pharmaceutical Manufacturers

I. Introduction

The Office of Inspector General (OIG) of the Department of Health and Human Services is continuing in its efforts to promote voluntary compliance programs for the health care industry. This compliance guidance is intended to assist companies that develop, manufacture, market, and sell pharmaceutical drugs or biological products (pharmaceutical manufacturers) in developing and implementing internal controls and procedures that promote adherence to applicable statutes, regulations, and requirements of the federal health care programs¹ and in evaluating and, as necessary, refining existing compliance programs.

This guidance provides the OIG's views on the fundamental elements of pharmaceutical manufacturer compliance programs and principles that each pharmaceutical manufacturer should consider when creating and implementing an effective compliance program. This guide is not a compliance program. Rather, it is a set of guidelines that pharmaceutical manufacturers should consider when developing and implementing a compliance program or evaluating an existing one. For those manufacturers with an existing compliance program, this guidance may serve as a benchmark or comparison against which to measure ongoing efforts.

A pharmaceutical manufacturer's implementation of an effective compliance program may require a significant commitment of time and resources by various segments of the organization. In order for a compliance program to be effective, it must have the support and commitment of senior management and the company's governing body. In turn, the corporate leadership should strive to foster a culture that promotes the prevention, detection, and resolution of instances of problems. Although an effective compliance program may require a reallocation of existing resources, the long-term benefits of establishing a compliance program significantly outweigh the initial costs.

In a continuing effort to collaborate closely with the pharmaceutical industry, the OIG published a notice in

¹ (Endnotes appear at end of document)