

Nondisclosure of Financially Sensitive Information #I92-1 (blue book memo) (Text Only)

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

Integrity Memorandum G92-1

Director, Office of Device Evaluation (HFZ-400)

Nondisclosure of Financially Sensitive Information

Office of Device Evaluation Review Staff

Purpose

The purpose of this memorandum is to clarify ODE's current policy concerning the disclosure or use of financially sensitive information.

Background

There has been increasing concern over the release or use of financially sensitive information concerning agency actions on submissions to FDA, including those to ODE. This financially sensitive information may be used by investors and others for the purpose of making decisions to buy or sell the stock of the firm that is the subject of the information or to buy or sell the stock of its competitors.

In response to these concerns, FDA contracted with the law firm of Kutak, Rock and Campbell to study this matter and the firm has provided FDA a draft final report commonly known as the "Strasser Report". The report contains many recommendations, including, but not limited to:

- new regulations dealing with employee disclosure of such information;
- broader FDA disclosure of such information to the public;
- improved employee training on these matters;
- improved employee reporting of financial ownership of outside interests;
- additional publication of advisory committee activities;

- the use of confidentiality agreements with other agencies prior to disclosure of sensitive information; and,
- increased liaison with securities enforcement agencies.

The agency ultimately will adopt policies, procedures, or regulations to implement some or all of the recommendations contained in the final report. Until that time, ODE will follow the policy set forth below concerning financially sensitive information. These policies are not entirely new and have, by and large, been followed by ODE staff for years.

"Financially Sensitive Information"

The Strasser Report contains the following working definition of "financially sensitive information":

... non-public information which could be reasonably expected to influence an investment decision by one having knowledge of the information, We include within this definition pre-market approvals, status of pending applications and petitions, identification of matters to be presented to advisory committees, activities related to seizures and recalls, the results of research activities, and other similar agency actions.

This is the best definition available at this time and we offer it to you for your guidance.

Policy

As a general rule, ODE staff may disclose financially sensitive information concerning FDA/ODE actions only to FDA and other DHHS employees. If financially sensitive information is being supplied to an FDA employee outside of the Office of Device Evaluation and the Office of Compliance and Surveillance, the recipient should be reminded that the information is sensitive and may only be disclosed to authorized individuals. Reviewers should discuss requests for financially sensitive information from employees in other DHHS agencies with their supervisors. Such information

should be disclosed only in the conduct of official business and after the recipient has been reminded that the information is sensitive and may only be disclosed to authorized individuals. From time to time, staff may be called upon to disclose such information to employees of federal agencies in other departments; this should be done only after discussing such disclosure with the office of the Director.

Staff should never disclose such information to anyone outside the federal government. Furthermore, staff should not discuss any agency activities with members of the financial community, e.g., stock brokers, market analysts, financial advisors, etc.

For your information, I am attaching a copy of the June 6, 1991 memorandum from Commissioner Kessler to all employees concerning the handling of sensitive and confidential information. In this memorandum, the Commissioner offered the following guidance:

I want to reemphasize that in your dealing with outside individuals, you must use extreme caution to prevent disclosing privileged information that has come into your possession by virtue of your government position, or that you have overheard or read through proximity to other government employees. Outside individuals may include representatives from trade associations, the regulated industry, stock analysts, industry consultants, or attorneys representing any of these groups or individuals. The review status of product approval applications (including New Drug Application, Abbreviated New Drug Application, New Animal Drug Application, Food Additive Petitions, 510(k)s, Pre-Market Applications), internal discussions about regulatory decisions, and recommendations about proposed or pending enforcement actions are some examples of information that must not be disclosed. In addition, FDA employees must use discretion to avoid giving advice or information that could be considered as preferential treatment to certain companies or individuals. If you are at all uncertain about the appropriateness of providing information on specific issues or matters to outside individuals, you should

refrain from doing so, and then discuss the matter with your supervisor.

Effective Date

This memorandum is effective immediately.

Robert L. Sheridan

Attachment

[More in Guidance Documents \(Medical Devices and Radiation-Emitting Products\)](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)
[\(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm\)](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

[Cross-Center Final Guidance](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)
[\(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm\)](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

[Office of Compliance Final Guidance](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)
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[Office of the Center Director Final Guidance](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)
[\(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm\)](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

[Office of Communication and Education Final Guidance](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)
[\(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm\)](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

[Office of Device Evaluation Final Guidance 2010 - 2016](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)
[\(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm\)](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

[Office of Device Evaluation Final Guidance 1998 - 2009](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)
[\(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm\)](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

[Office of Device Evaluation Final Guidance 1976 - 1997](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)
[\(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm\)](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

[Office of In Vitro Diagnostics and Radiological Health Final Guidance](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)
[\(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm\)](/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)