“513(g)s”…
Including 513(g) User Fees

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At the End of this Module . . .

One should know:

- **What is a 513(g) Request for Information**
- **What questions may be asked under the 513(g) Process**
- **What Opinions are given to 513(g) Requests**
- **How to put together a 513(g) Request**

Section 513(g) of the Act

- **“Within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this Act, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device.”**

Section 513(g) of the Act

- "Within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this Act**, the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device."**

513(g) “Typical” Inquiries

- To date, most inquiries are submitted to:
  - Determine whether a product is subject to FDA regulations.
  - Determine whether a device is exempt from the 510(k) requirements of the Act.
  - Determine whether a 510(k) is needed for a modification to one's device.
  - Determine the least burdensome regulatory pathway for a device, which introduces a new technology or a new intended use.

513(g) Yearly Submissions

Calendar Year	Submissions
1990	4
1995	12
2000	69
2002	117
2004	290
2007	364
2008 (as of 10/08)	43

Current Change to the 513(g) Review Process

- Charging of User fees in FY 10:

  - 510(k) Std. Fee $4,007.00
  - 513(g) Std. Fee $2,941.00

  - 510(k) Small Business Fee $2,004.00
  - 513(g) Small Business Fee $1,470.00

Section 513(g) of the Act

- **“Within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under this Act,** the Secretary shall provide such person a written statement of the classification (if any) of such device and the requirements of this Act applicable to the device.”30

FDA responses to requests for information about the regulatory requirements applicable to a particular device DO NOT constitute FDA clearance or approval for distribution of that particular device in the United States.

OPINIONS* offered as responses to 513(g) Requests on Software

- Classified device requiring a 510(k) submission – 34
- Classified device exempt from 510(k) requirements – 16
- Unclassified device requiring a 510(k) submission - 9
- Unclassified device under enforcement discretion - 6
- Not a device - 6
- General purpose article - 2
- Drug regulated by CDER - 2
- Biologic regulated by CBER - 1
- Classified device requiring a PMA submission - 1
- Not a finished device - 1

* - May not be the sole opinion given in response to a request.

Contents of a 513(g) Request:

- A Cover Letter.
- A complete Device Description.
- A concise Indication(s) for Use Statement.
- Either proposed labeling or labeling of a marketed similar product/device.

Mailing Address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center, WO-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

ORIGINAL AND ONE COPY PLEASE

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