

DEPARTMENT OF HEALTH AND HUMAN SERVICES

MEMORANDUM

Food and Drug
Administration
Office of Device Evaluation
9200 Corporate Boulevard
Rockville, MD 20850

Date: August 12, 1998
From: Keith E. Foy
To: Panel Members
Subject: Guidance Document for Neurological Embolization Devices (DRAFT)

Dear Panel Member:

At the Neurological Devices Advisory Panel (the Panel) meeting scheduled for September 16 and 17, 1999, you will be involved in a general discussion of the draft guidance on neurological embolization devices (attached). This document is not final nor is it in effect at this time. The purpose of this document is to provide guidance to sponsors of neurological embolization devices on important preclinical, clinical, and labeling information that should be presented for premarket notification (510(k)), investigational device exemption (IDE) and premarket approval (PMA) submissions. The preliminary background document discusses issues relevant to preamendments class III 510(k) products such as polyvinyl alcohol (PVA) particles, detachable balloons and embolization coils and post amendment and/or transitional class III PMA products, such as cyanoacrylates. Please review the guidance document and the accompanying questions for discussion at this time.

If you have any questions about the preliminary background document you may contact Mr. Keith E. Foy, Reviewer, Plastic and Reconstructive Surgery Devices Branch at (301) 594-3090 ext 132.

Please contact Ms. Jan Scudiero, Executive Secretary for the Neurological Devices Panel, at 301-594-1184, for questions regarding the scheduled panel meeting.

Sincerely yours,

Keith E. Foy, M.S.
Reviewer
Plastic and Reconstructive Surgery Devices Branch