

DMB

Display Date 3-28-03@2:27
Publication Date 4-1-03
Certifier N. Hawkins

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

1491 '03 APR -1 09:50

[Docket No. 03N-0014]

Draft Guidance on Human Subject Protection; HHS Request for Comments

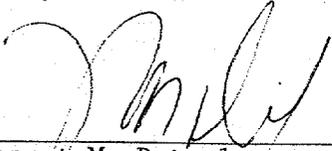
AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of solicitation of comments by HHS.

SUMMARY: The Food and Drug Administration (FDA) is announcing that elsewhere in this issue of the **Federal Register** the Department of Health and Human Services, Office of the Secretary, Office of Health and Science is soliciting public comment on a draft guidance document for Institutional Review Boards, investigators, research institutions, and other interested parties, entitled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection." This draft guidance document raises points to consider in determining whether specific financial interests in research affect the rights and welfare of human subjects, and if so, what actions could be considered to protect those subjects. This draft guidance applies to human subjects research conducted or supported by HHS or regulated by FDA.

DATES: HHS is accepting written or electronic comments on the draft guidance until 4:30 PM on *[insert date 60 days after date of publication in the Federal Register]*.

Dated: 2/10/03
January 21, 2003.



Margaret M. Dotzel,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

