DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

August 28, 2001

1357 '01 AUG 30 P1:50

Anjo den Decker-deBliek
Training Coordinator
Kendle International BV
Bolognalaan 40
3584 CJ Utrecht
The Netherlands

Dear Anjo den Decker-deBliek,

Your letter to the Food and Drug Administration (FDA), Dockets Management Branch, regarding the Guideline for Monitoring of Clinical Investigations (Guideline) was sent to me for response.

The two items you identified in your letter have been corrected in the current version of the Guideline which is posted on FDA's website. Specifically, the first item that you noted regarding a redundant "and current," has been corrected to read, "Accurate, complete and current records are being maintained." The second mistake you identified was corrected to read, "Accurate, complete, and timely ***reports*** are being made to the sponsor and IRB."

You may view the Guideline on FDA's website, at the following URL:

http://www.fda.gov/cder/guidance/index.htm

If you go to the "Compliance" section, the guideline is #9 in the list.

I hope this information is helpful to you. If you have any additional questions, please do not hesitate to contact this office.

Sincerely,

Carolyn L. Hommel
Consumer Safety Officer
Division of Scientific Investigations (HFD-45)
Office of Medical Policy
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
e-mail: hommelc@cder.fda.gov

82D-0322

ANS 2
See C6

cc: chron
HFA-224

AUGUST 03, 2001 DOCKET NUMBER: 82D-0322

L INVESTIGATIONS;AVAILABILITY GUIDELINE FAP/CAP/GRASP Number:

ED D YY	P C	SUBMITTER	FR DATE	FR PAGE	COM/OBJ MM DD YY	VOL	MISCELLANEOUS
6/88		Signature:	02/17/88	4723		1	
6/88	C	ABIOMED, INC Signature:				1	
0/88	E	DUNCAN, D (HFR-MW-2560) Signature:				1	
2/88	C	MAYO CLINIC Signature:				1	
2/88	C	IMMUNO-US INC/OFFICE OF THE MED DIREC Signature:				1	
6/88	D	ANIMAL HEALTH INSTITUTE Signature:				1	
1/89	C	Spectrum Medical Market Consultants Inc. Signature: J. Wayne Bryant, CBC				1	
0/91	C	St. Francis Medical Center Signature: Douglas Massey, M.D., Chairman				1	
4/91	E	HFD-360 Signature: Marilyn L. Watson				1	SEE LET2
5/01	I	Kendle International BV Signature: Anjo den Decker - de Blick				1	

Kendle

Dockets Management Branch (HFA-305)
Food and Drug Administration
Docket Number 82D-0322
5630 Fishers Lane
Rockville, MD 20857

Jan 1988
HFC-230

Reference: E01-2064\AD

Utrecht, July 25, 2001

Re: Guidance for Industry: Guideline for the Monitoring of Clinical Investigations

Dear Sir, Madam,

I have two questions with respect to the above-mentioned document. On page three under the paragraph 'Periodic Visits', it is stated the monitor should visit the investigator at site of the investigation frequently enough to ensure that:

- Accurate, complete, and current and current records are being maintained.
- Accurate, complete, and timely reported are being made to the sponsor and IRB.

I assume that in the first sentence the wordings 'and current' are entered duple and that I can delete one entry without harming the contents of the text?
Furthermore I am wondering if a word (e.g. AEs) is missing after 'timely reported' in the second sentence or if the word reported must be replaced by reports?

Could you be so kind to respond my questions at your earliest convenience?

Yours sincerely,
Kendle International BV

Anjo den Decker – de Bliek
Training Co-ordinator

Cc. Dragos V. Budinski, Kendle UK

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82D-0322

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and (4) the maintenance of records of visits to the investigator including the findings, conclusions, and actions taken to correct deficiencies.

The guideline entitled "Guideline for the Monitoring of Clinical Investigations" is being made available under § 10.90(b) of FDA's administrative practices and procedures regulations (21 CFR 10.90(b)). Section 10.90(b) provides for the use of guidelines to establish procedures of general applicability that are not legal requirements but are acceptable to FDA. As provided in § 10.90(b)[1][i], sponsors who follow the guideline may be assured that it represents monitoring procedures acceptable to the agency. If a sponsor believes that alternative procedures may also suffice, the guideline does not preclude a sponsor from pursuing alternative procedures. Thus, sponsors are permitted flexibility to enable them to alter their monitoring procedures for a particular study, if necessary, while still complying with the intent of FDA's regualtions, i.e., to assure the protection of the rights of human subjects and the safety of all subjects and the quality and integrity of the test data. A sponsor who elects to use alternative procedures for monitoring a clinical investigation may, but is not required to, submit those procedures to FDA for review and comment to avoid the possibility of employing monitoring procedures that FDA might later determine to be inadequate to assure the protection of the rights of human subjects and the safety of all subjects involved or the quality and integrity of the data resulting from a clinical investigation. Sponsors wishing to obtain such a review should contact the Bioresearch Program Coordinator (address above).

Copies of the guideline can be obtained from the Bioresearch Program Coordinator (HFC-230), address above. A single copy of the guideline is on file with the Dockets Management Branch (address above) under the docket number found in brackets in the heading of this document and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

Interested persons may, at any time, submit to the Dockets Management Branch written comments regarding the guideline. Such comments will be considered in determining whether amendments to or revisions of the guideline are warranted. Two copies of any comments should be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 21, 1988.

Frank E. Young,

Commissioner of Food and Drugs.

[FR Doc. 88-3253 Filed 2-16-88; 8:45 am]

BILLING CODE 4160-01-M

Advisory Committees; Meetings

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: This notice announces forthcoming meetings of public advisory committees of the Food and Drug Administration (FDA). This notice also summarizes the procedures for the meetings and methods by which interested persons may participate in open public hearings before FDA's advisory committees.

Meetings: The following advisory committee meetings are announced:

Cardiovascular and Renal Drugs Advisory Committee

Date, time, and place. March 3 and 4, 1988, 9 a.m., National Institutes of Health, Jack Masur Auditorium, Bldg. 10, 9000 Rockville Pike, Bethesda, MD.

Type of meeting and contact person. Open public hearing, March 3, 1988, 9 a.m. to 10 a.m., unless public participation does not last that long; open committee discussion, 10 a.m. to 5 p.m.; March 4, 1988, open committee discussion, 9 a.m. to 5 p.m.; Joan C. Standaert, Center for Drug Evaluation and Research (HFN-110), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4730 or 419-529-6211.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of marketed and investigational prescription drugs for use in the treatment of cardiovascular disorders and diseases.

Agenda—Open public hearing. Interested persons requesting to present data, information, or views, orally or in writing, on issues pending before the committee should notify the committee contact person.

Open committee discussion. The committee will discuss (NDA 18-981/S-001) enkaid (encainide HCl), Bristol Myers Pharmaceuticals for treatment of supraventricular tachyarrhythmia; (NDA 12-093/S-26) and (NDA 19-517) isordil (isosorbide dinitrate), oral and parenteral, Wyeth Laboratories, for treatment of congestive heart failure, and guidelines for the study of anti-anginal agents.

Obsterics-Gynecology Devices Panel

Date, time, and place. March 29, 1988, 9 a.m., Rm. 503A-529A, Hubert H. Humphrey Bldg., 200 Independence Ave. SW., Washington, DC.

Type of meeting and contact person. Open public hearing, 9 a.m. to 10 a.m.; open committee discussion, 10 a.m. to 5 p.m.; Colin M. Pollard, Center for Devices and Radiological Health (HFZ-470), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7555.

General function of the committee. The committee reviews and evaluates available data on the safety and effectiveness of devices and makes recommendations for their regulation.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the committee contact person before March 11, 1988, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The Panel will discuss a premarket approval application for a contraceptive tubal occlusion device and provide FDA with its recommendation.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.