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The importance of device accountability

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The Importance of Device Accountability

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NATIONAL LEADERS IN MEDICINE

Financial Disclosures

Scientific Advisory Board

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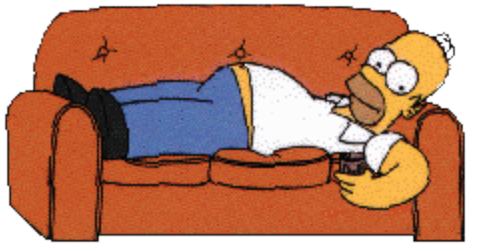
- NINDS

Acknowledgements

Kim Striler RN, MSN, CCRC, Clinical Research Specialist. Division of Cardiology, Washington University School of Medicine

Why are we talking about this?

- Use of commercially available product for an IDE trial - identical device may be on the shelf (sloppy)

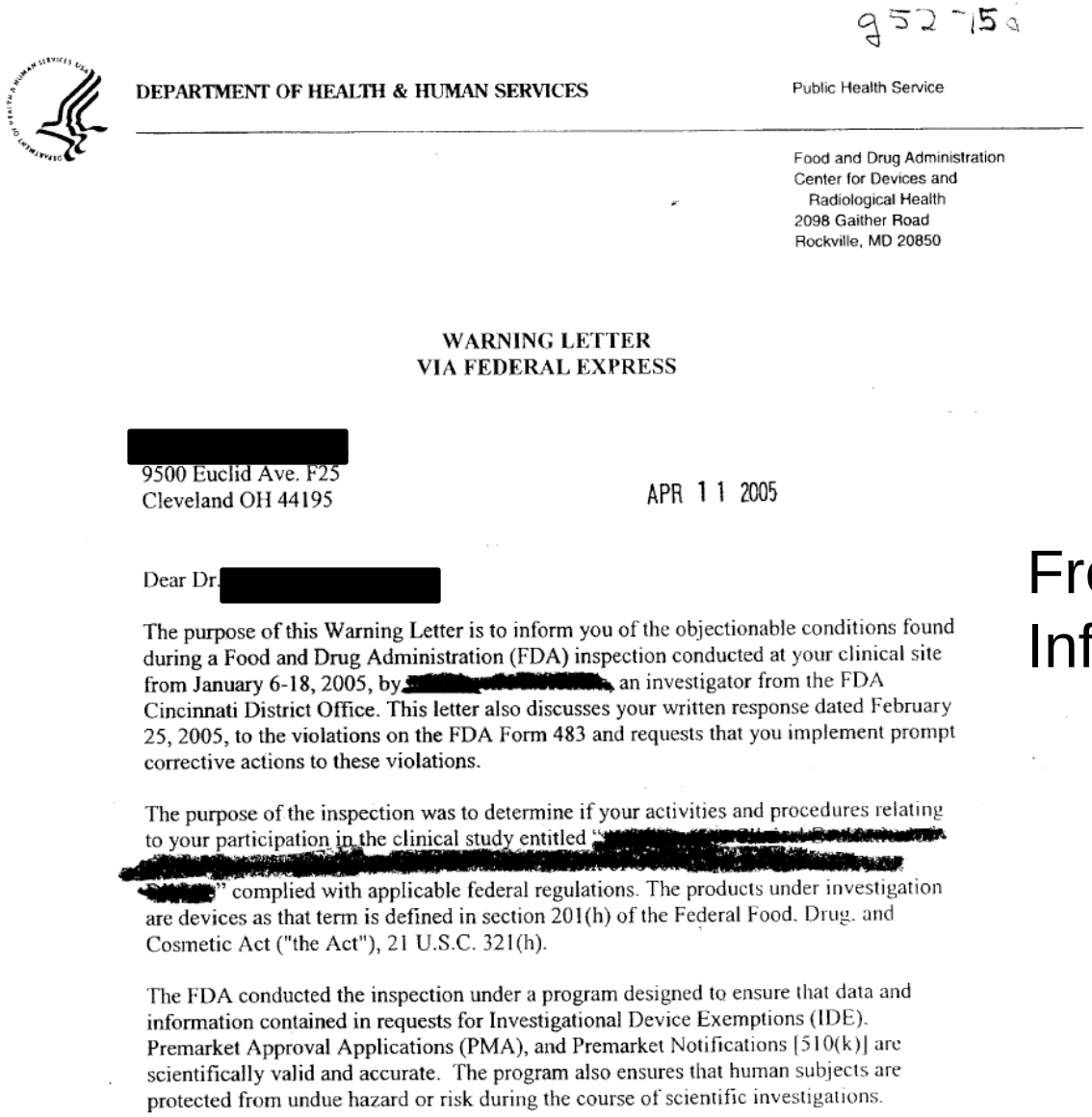


- Use of an IDE product outside of the trial (temptation)

Purpose of Device Accountability

- Both misuses create real problems
- Protect the rights, safety and welfare of research subjects and patients by ensuring the control and accountability of investigational devices used in clinical research
- Protect data integrity
  - Safety and efficacy or substantial equivalency cannot be established if study devices not used

Consequences



952-15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER
VIA FEDERAL EXPRESS

[redacted]
9500 Euclid Ave. F25
Cleveland OH 44195

APR 11 2005

Dear Dr. [redacted]

The purpose of this Warning Letter is to inform you of the objectionable conditions found during a Food and Drug Administration (FDA) inspection conducted at your clinical site from January 6-18, 2005, by [redacted], an investigator from the FDA Cincinnati District Office. This letter also discusses your written response dated February 25, 2005, to the violations on the FDA Form 483 and requests that you implement prompt corrective actions to these violations.

The purpose of the inspection was to determine if your activities and procedures relating to your participation in the clinical study entitled "[redacted]" complied with applicable federal regulations. The products under investigation are devices as that term is defined in section 201(h) of the Federal Food. Drug. and Cosmetic Act ("the Act"), 21 U.S.C. 321(h).

The FDA conducted the inspection under a program designed to ensure that data and information contained in requests for Investigational Device Exemptions (IDE). Premarket Approval Applications (PMA), and Premarket Notifications [510(k)] are scientifically valid and accurate. The program also ensures that human subjects are protected from undue hazard or risk during the course of scientific investigations.

Freedom of Information Act

Stroke and Cerebrovascular Center

BARNES-JEWISH Hospital BJC HealthCare | Washington University in St. Louis Physicians

NATIONAL LEADERS IN MEDICINE

Consequences

1. You failed to report the use of non-investigational [redacted] in 12 of the [redacted] subjects as required by FDA regulations and the guidelines set forth by your IRB. Non-investigational [redacted] were used during the index procedure for 15 of the [redacted] subjects enrolled in the study. As of January 6, 2005, the IRB had been notified of the use of non-investigational stents in only 3 of these [redacted] subjects ([redacted]

   The protocol deviation procedure of your IRB states that deviations from the investigational plan by the investigator or support personnel should be reported promptly to the IRB. The use of non-investigational stents is a deviation from the investigational plan; this deviation was not reported promptly to the IRB. The IRB was not informed of the use of all of the non-investigational stents in this study until the FDA inspection took place. Examples include the following:

   A [redacted] received commercial/non-investigational [redacted] in conjunction with the [redacted] during their index procedure. The use of these non-investigational [redacted] is a protocol deviation that was not reported promptly to the IRB and sponsor.

   B. [redacted] was treated with an investigational [redacted] in the [redacted] during the index procedure on [redacted]. On [redacted] the subject then received a non-investigational [redacted] in the ri[redacted] 28 days after the index procedure. This subject was treated despite meeting an exclusion criterion which excludes those subjects where "there is a planned combination procedure involving either the contra lateral carotid artery, a coronary artery, or peripheral artery 30 days before or after the index procedure". These protocol deviations were not reported to the IRB and sponsor as required by your IRB policy and FDA regulations [21 C.F.R. 812.150(a)(4)].

   Your written response states that the study coordinator misunderstood the IRB policy. and that the use of these non-investigational [redacted] was reported to the IRB prior to the completion of the FDA inspection. While this task may be delegated. it is the

Investigator Responsibilities

- Control of the investigational device used in the study
- Ensure the device is stored in a secure area
- Ensure device is used only in patients that consented to participate in the trial
- Ensure device is used according to the IRB-approved protocol
- Ensure records related to the receipt, use and disposition of the device are adequately maintained

Receipt and Inventory

- Inventory typically shipped to coordinator
- Upon receipt of the investigational device inventory the shipment, confirm the information on the packing slip matches the contents including:
  - Quantity
  - Lot numbers
  - Expiration date
  - If a discrepancy is noted, contact the sponsor immediately and return any damaged, defective or discrepant devices
  - File packing slip in the device binder

Device accountability log

Once the inventory is complete and confirmed, enter the data into the device log including:

- Date of receipt
- Serial and/or lot number
- Expiration date
- Name or identifiers of person who receives device
- Ensure all entries are legible.

Device accountability log

Site Name: Washington University School of Medicine
Site Number: 1234
Principal Investigator: Fred Stent, MD

TO THE INVESTIGATOR:

1. PLEASE MAINTAIN THIS LOG THROUGHOUT THE STUDY. EACH TEST ARTICLE MUST BE ITEMIZED INDIVIDUALLY BELOW.
2. ALL DEVICES RECEIVED BY THE INSTITUTION OR INVESTIGATOR MUST BE ACCOUNTED FOR WHETHER USED OR NOT.
3. AT THE COMPLETION OF THE STUDY, PLEASE RETURN ANY UNUSED DEVICES TO THE ADDRESS SHOWN BELOW:

   Stent Company
   1234 Stent Street
   Stent Town, MO 12345

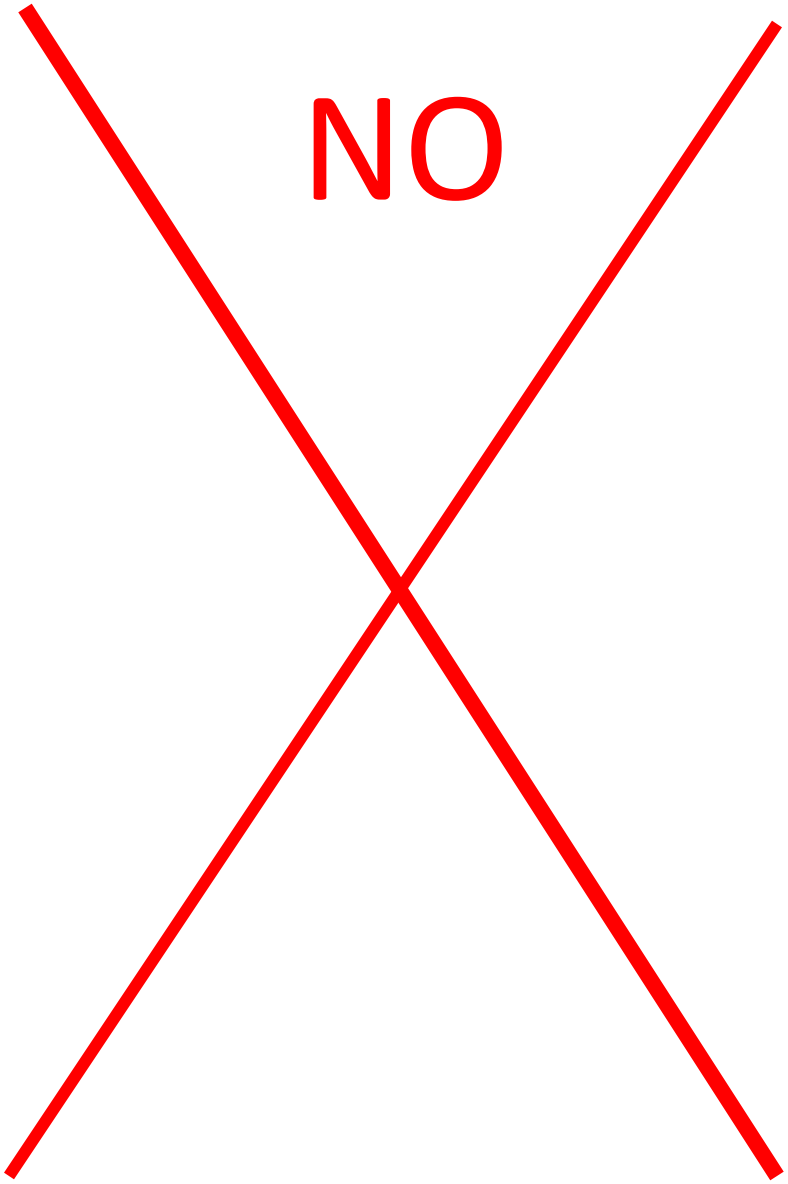
4. AT THE COMPLETION OF THE STUDY, PLEASE KEEP A COPY IN YOUR RECORDS AND RETURN THE ORIGINAL TO The Sponsor

DATE OF RECEIPT (mm/dd/yy) initials	SERIAL NUMBER	Use By Date	SIZE	DEVICE DISPOSITION D = DISCARDED R = RETURNED TO SPONSOR I = Implanted	DISPOSITION DATE (mm/dd/yy) initials	PATIENT STUDY NUMBER	COMMENT (EXPLAIN IF DEVICE WAS DISCARDED, RETURNED TO SPONSOR OR OTHER INCLUDE RGA # AND FED EX #)
1/24/11 KAS	123678	2/22/12	4.0 x 12	☐ D ☐ R ☐ I ☐ other		☐ N/A	
1/24/11 KAS	155001	6/1/12	3.5 x 16	☐ D ☐ R ☐ I ☐ other		☐ N/A	
1/24/11 KAS	155332	10/1/11	2.5 x 22	☐ D ☐ R ☐ I ☐ other		☐ N/A	
				☐ D ☐ R ☐ I ☐ other		☐ N/A	

Storage of Device

- Store investigational device in a secure location with access limited to the essential research personnel
- Device must be kept in a locked closet or cabinet

Storage of Device



YES

Dispensing Devices

Each time a device is dispensed by the Investigator or a member of the research team, the device log must be updated. This includes:

- Device disposition
- Date of disposition
- Patient study number
- Initials of individual dispensing

Dispensing Devices

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1/24/11 KAS	155001	6/1/12	3.5 x 16	☐ D ☐ R X I ☐ other	1/27/11 KAS	☐ N/A 1234-002	
1/24/11 KAS	155332	10/1/11	2.5 x 22	☐ D ☐ R ☐ I ☐ other		☐ N/A	
				☐ D ☐ R ☐ I ☐ other		☐ N/A	

Dispensing Devices

SPONSOR: STENT Company	TRIAL NAME: The New Stent Trial	Device: New Stent	Device Accountability Log Page 1 of _____

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1/20/11 FS	13684	1/11/13	☒ 23 ☐ 26	☐ D ☐ R ☒ I ☐ other	1/26/11 FS	☐ N/A 1234-001	
	13861		☐ 23 ☒ 26	☐ D ☐ R ☒ I ☐ other		☐ N/A 1234-002	
	14822		☐ 23 ☐ 26	☐ D ☒ R ☐ I ☐ other		☐ N/A	Returned
	14864		☐ 23 ☐ 26	☒ D ☐ R ☐ I ☐ other		☐ N/A	

*If discarded, returned to sponsor or other, please explain in the comment section

er

Return or Disposal of Device

- Unused devices will be returned to the sponsor at the end of the trial or if they expire
- Contact the sponsor to obtain a RGA # (returned goods authorization number)
- Log out the devices on the accountability log including the return date and Fed Ex number
- If a device is discarded for any reason, this must also be entered into the device log

Return or Disposal of Device

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1/24/11 KAS	155332	10/1/11	2.5 x 22	☐ D X R ☐ I ☐ other	2/1/11 KAS	X N/A	Returned to sponsor, end of study RGA # 12556788 Fed Ex # 123456789-00
				X D ☐ R ☐ I ☐ other	1/27/11 KAS	X N/A	Device opened, contaminated, unused and discarded in the trash

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