About FDA

Alkis Togias, M.D./Johns Hopkins Asthma & Allergy Clinic, Baltimore, MD.: FDA 483 Inspectional Observations; (Baltimore) 06/28/2001

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
900 Madison Avenue
Baltimore, MD 21201
410-962-3396

DATE(S) OF INSPECTION

6/18,19,20,21,28/01

FEI NUMBER

3003350724

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Alkis Togias, MD, Associate Professor of Medicine

FIRM NAME

Johns Hopkins Asthma & Allergy Clinic

STREET ADDRESS

5501 Hopkins Bayview Circle

CITY, STATE AND ZIP CODE

Baltimore, MD 21224

TYPE OF ESTABLISHMENT INSPECTED

Clinical Investigator

DURING AN INSPECTION OF YOUR FIRM, I OBSERVED:

The following observations are related to RPM No.: AACOO-07-26-02, entitled, "Mechanisms of Deep Inspiration-Induced Airway Relaxation."

1. This sponsor/clinical investigator failed to submit an IND to the FDA prior to conducting this clinical investigation, which involved the administration of hexamethonium bromide by inhalation to 3 human subjects.

2. The sponsor/clinical investigator failed to report an unanticipated adverse event to the IRB.

   The first subject in the study, , was administered hexamethonium on 4/23/01. She developed a persistent cough from 4/25/01 till 5/3/01. The IRB was not notified of this event.

3. Failure to follow the protocol in that the protocol stated that hexamethonium would be administered by inhalation, when in fact; hexamethonium and sodium bicarbonate were actually administered to the second and third subjects.

4. This sponsor/clinical investigator made changes to the approved protocol, dated 9/18/00, without notifying the IRB and without IRB approval, for example:

   a.The sponsor/clinical investigator added sodium bicarbonate to the hexamethonium to change its pH, for the second and third subjects, without notifying and obtaining approval from the IRB. There were no records available for review to determine how much sodium bicarbonate was added.

   b. The protocol approved by the IRB, dated 9/18/00, stated that the "subjects will be premedicated with either hexamethonium, or its vehicle (normal saline), by inhalation." The clinical investigator administered 4.5% hyperosmolar saline instead of the normal saline.

5. Failure to obtain effective informed consents from subjects, in that the sponsor/clinical investigator failed to disclose that inhalation administration of hexamethonium was an experimental use of the drug.

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
SEE REVERSE OF THIS PAGE			6/28/01

J. Diann
Shaffer,
Investigator

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