The Inspection is Over – What Happens Next?

Possible FDA Enforcement Actions

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The End of the Inspection

- Form FDA-483 is presented and discussed
- You may respond in a letter - send to address on the Form FDA-483.
- You may also ask the FDA investigator for the HQ Center address

- The inspection report is written by the FDA investigator and sent to the Center.
- The Center evaluates the report and determines the corrective action.
- We write a letter following most inspections

The Center Classifies the Inspection

- NAI No Action Indicated
- VAI Voluntary Action Indicated
- OAI Official Action Indicated

Possible Actions for OAIs

- Actions for Inspected Party
- Actions on Applications

Actions for Inspected Party

Warning Letter

- One or more activities is in violation of laws or regulations.
- Failure to take action may result in administrative or regulatory action without further notice
- 15 day response
- Posted on FDA web page

Actions for Inspected Party
Initiate CI Disqualification

- Notice of Initiation of Disqualification Proceeding and Opportunity to Explain (NIDPOE)
- Posted on FDA web page
- Disqualified investigators may not receive investigational products
- No requirement to issue warning letter before NIDPOE

Actions for Inspected Party

- Refer to FDA Office of Criminal Investigations
- Injunction
- Seizure
- Prosecution

  Debarment if convicted of felony on FDA-related charges

U.S. Department of Justice

Michael J. Sullivan
United States Attorney
District of Massachusetts

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PRESS RELEASE

CLINICAL STUDY COORDINATOR FOR PEDIATRIC DRUG SENTENCED FOR FRAUD

Boston, MA... A Newton woman was sentenced today in federal court for making false statements in connection with a Food and Drug Administration approved clinical study.

United States Attorney Michael J. Sullivan and Kim A. Rice, Special Agent in Charge of the Food and Drug Administration's Office of Criminal Investigations, Metro Washington Field Office, announced today that **ANNE BUTKOVITZ**, age 48, of Newton, Massachusetts, was sentenced by U.S. District Judge Douglas P. Woodlock to 1 year of probation and a $1,000 fine. **BUTKOVITZ** pleaded guilty on June 7, 2005, to an Information charging her with one count of making false statements. As part of her plea agreement with the Government, **BUTKOVITZ** also agreed that she would never participate in any manner in the conduct of studies intended for or required for submission to the FDA.

Actions on Applications

Clinical Hold

The Center may impose a clinical hold of a drug/biologic study *21 CFR 312.42*

Or

Disapprove a device study

21 CFR 812.30

Actions on Applications
Reject the Data

- FDA may determine that the data are unreliable (inaccurate / incomplete)
- The remaining data would need to be reanalyzed.
- Might require an additional study
- Might delay approval of a BLA/NDA/PMA

Actions on Applications
Terminate IND / Withdraw IDE

- Ends all studies
- Sponsor recalls all unused drugs/devices
- Unless immediate hazard, requires Part 16 hearing

Actions on Applications

Withdraw Approval of NDA and PMA

Revoke BLA

Actions on Applications

Application Integrity Policy

- Agency will defer substantive review of applications
- Untrue statements of material facts; pattern or practice of wrongful acts; bribes
- Require corrective action plan

How to Find Investigator Inspection History

CDER

http://www.fda.gov/cder/Offices/DSI/ClinInvestList.htm

CBER

http://www.fda.gov/cber/compl/clininvlist.htm

CDRH

Submit request under Freedom of Information Act

FDA's Electronic Freedom of Information Reading Room

www.fda.gov/foi/electrr.html

- Warning letters
- Clinical Investigators
  - NIDPOEs and NOOHs
  - Disqualified and restricted CIs
  - Presiding officer decisions
- Firms under Application Integrity Policy

Compliance References

www.fda.gov/ora/compliance_ref

Regulatory Procedures Manual

warning letters, untitled letters, judicial actions

Application Integrity Policy

Debarment list

Bioresearch Monitoring compliance programs

www.fda.gov/oc/gcp/

Good Clinical Practice references

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