

Sharing Non-Public Information

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Agenda

- Overview of the FOIA
- Relevant FOIA Exemptions and Examples
 - Exemption 4: Confidential Commercial Information and Trade Secrets
 - Exemption 5: Internal Deliberations
 - Exemption 6: Personal Privacy
 - Exemption 7: Law Enforcement Records
- Additional Resources

Freedom of Information Act

5 USC 552

- Provides for the sharing of agency records with the public.
- FOIA is a disclosure statute, but has 9 exemptions for non-public information.
 - FDA has regulations in 21 CFR Part 20 that mirror the exemptions.
- Sharing with states, local governments, and other federal agencies occurs outside of the FOIA, but has the same concepts of non-public information.

Exemption 4 of the FOIA

- Exemption 4 prohibits the release of confidential commercial and trade secret information to the public. This protects the financial interests of the information owner and prevents competitive harm.
- Examples of CCI:
 - Customer/Supplier relationships (i.e. distribution channel information)
 - Sales data
 - Consultants or contractors
 - Pending product approval records
 - Future business plans
- Examples of TS:
 - Formulations
 - Chemical composition
 - Quality control procedures
 - Sterilization and cleaning procedures
 - Production procedures

Exemption 5 of the FOIA

- Exemption 5 protects from disclosure:
 - Internal, pre-decisional deliberations
 - Records within the attorney/client privilege
 - Attorney work product (records prepared in anticipation of litigation)
- It is a discretionary exemption.
 - FDA can waive its exemption
 - If challenged, government must show “foreseeable harm” from release

Exemption 6 of the FOIA

- Exemption 6 prohibits the release of information that would constitute an unwarranted invasion of personal privacy.
- Balance of the public's right to know against the individual's right to privacy.
- Examples of PPI:
 - Patient medical records
 - Personal information on adverse event report
 - Employee home address or personal cell phone
 - Identity of complainant

FOIA Exemption 7

- Exemption 7 protects from disclosure certain types of law enforcement records, including:
 - Records that could reasonably be expected to interfere with enforcement proceedings (discretionary);
 - Records that could reasonably be expected to constitute an unwarranted invasion of personal privacy (similar to Exemption 6);
 - Records that could reasonably be expected to disclose the identity of a confidential source;
 - Records that would disclose techniques and procedures for law enforcement investigations (discretionary)

Additional Information

- DOJ FOIA Guide:

http://www.justice.gov/oip/04_3.html

- FDA FOIA Website:

<http://www.fda.gov/RegulatoryInformation/FOI/ReferenceMaterials/default.htm>