Freedom of Information Act (FOIA): Accessing FDA/CDRH Records

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Objectives

Understand FOIA Basics Basics

Legal foundation for transparency

Identify Available Records

FDA/CDRH documents accessible through FOIA

Master Search & Request Process

Efficient search methods and submission procedures

https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/readingroom.cfm

FOIA – Freedom of Information Act

Established History

Enacted 1966, amended 2016

Record Access

Public access to federal agency information

Government Transparency

Promotes accountability in operations

https://www.justice.gov/oip/freedom-information-act-5-usc-552

CDRH & FOIA

510(k) Summaries

Device clearance showing substantial equivalence

PMA Decisions

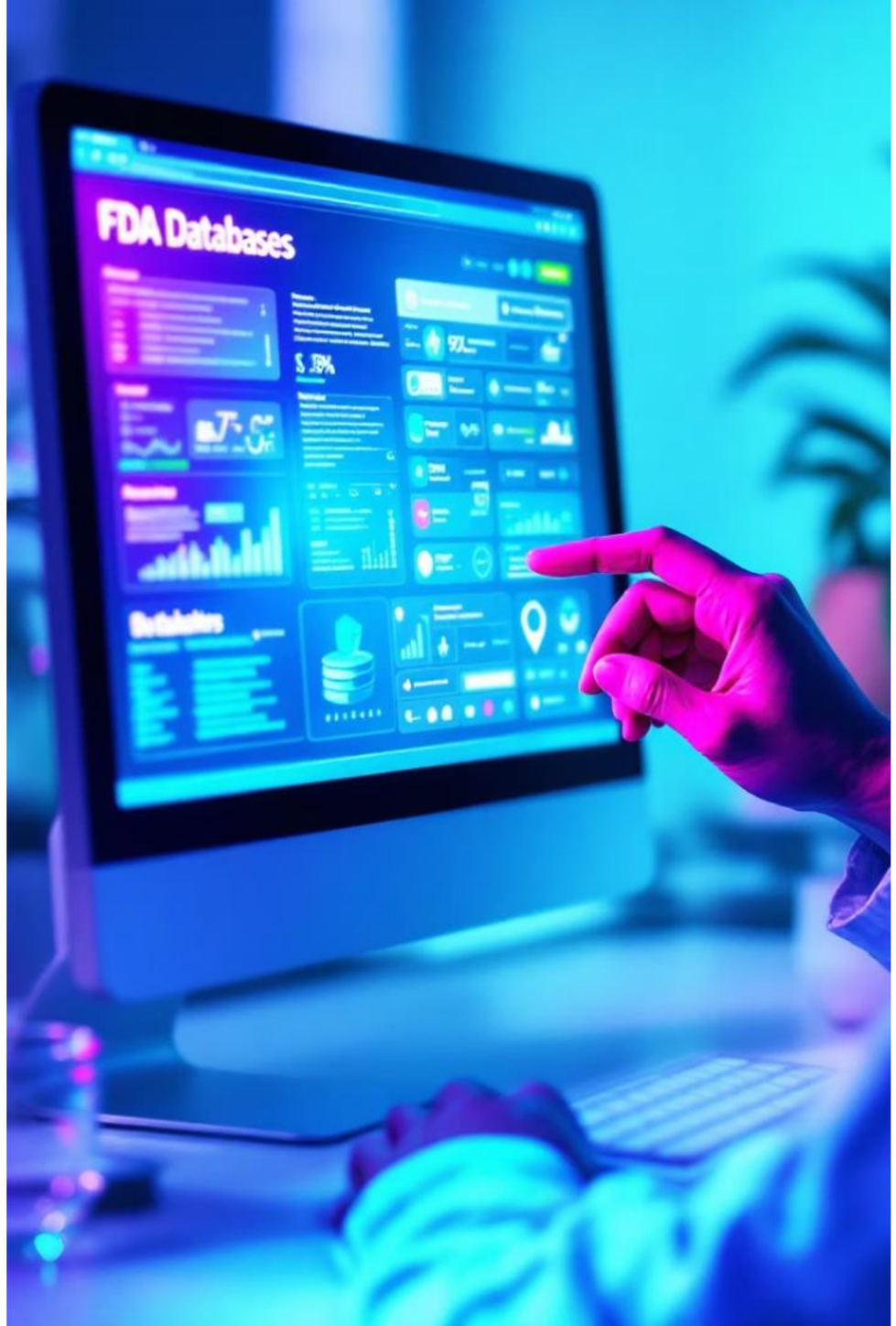
Premarket approval for Class III devices

Adverse Event Reports

Safety information on device incidents

Inspectional Records

Facility inspection and compliance documentation



Search Before Submitting FOIA

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/search.cfm

510(k) Database

Device clearance information

MAUDE System

Adverse events database

PMA & De Novo Portals

Class III and novel device approvals

https://www.accessdata.fda.gov/scripts/cdrh/devicesatfda/readingroom.cfm

How to Submit a FOIA Request Request

Prepare Request

Include contact info and specific record details

Include Fee Statement

State payment willingness or request waiver

Submit Request

Use FDA's online FOIA portal for fastest processing

http://www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm

Where to Send FOIA (Offline)

Mailing Address

FDA Division of FOI, ODIGA

5630 Fishers Lane, Room 1035

Rockville, MD 20857

Contact Information

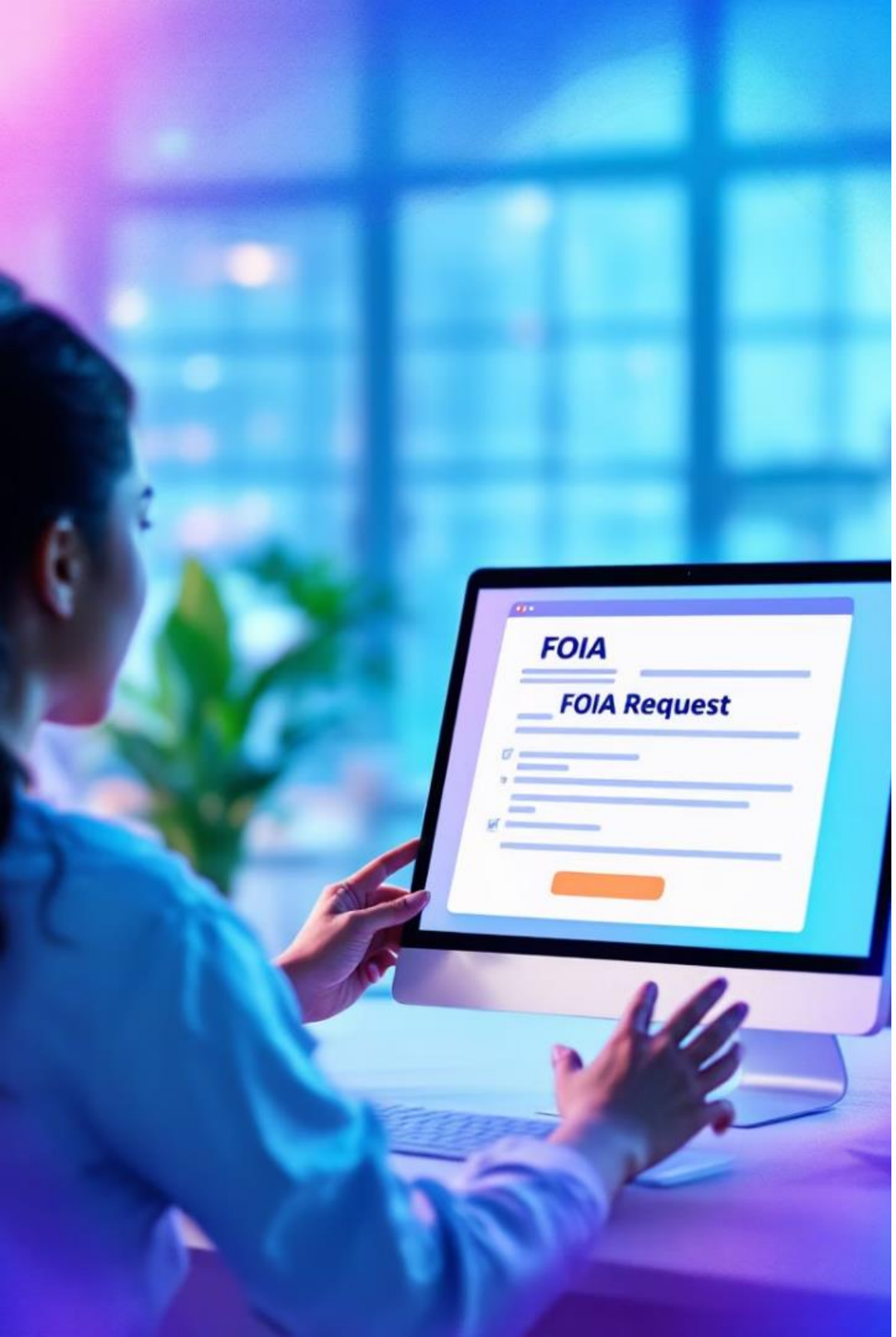
Phone: 301-796-3900

Email: CDRH-FOIStatus@fda.hhs.gov

NEW! Requesters can now submit a FOIA request online:

http://www.accessdata.fda.gov/scripts/foi/FOIRequest/index.cfm

Response times vary by complexity



How to Send FOIA (Online)

First Party Requests

State if requesting personal records

Consumer Complaints

Don't use FOIA form for complaints

Required Fields

Fill all fields marked with asterisk

Documentation

Attach request letter as PDF or DOC

https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm

How to Send FOIA (Online)

First Party Requests
- If requesting your own records: state it's a first-party request and provide documentation.
- If requesting records about someone else: include a signed authorization from that person or organization

Consumer Complaints
- Do NOT use the FOIA form to submit complaints.
- Submit complaints separately at: FDA Consumer Complaints

FOIA Request Instructions
- All required fields (*) must be filled
- Valid email is required
- Use Subject field for a clear description
- You may attach a request letter (PDF, DOC)
- Be specific and detailed in what you request
- You can submit multiple requests per login
- After submitting: you'll receive a confirmation number
- FDA will email an Acknowledgment Letter with your FOIA Control

https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm

FOIA Fees Overview

$29-102	**Commercial Search**	Per hour rate
$0.10	**Duplication**	Per page cost
100	**Educational/Media**	Free pages, no search fee
2	**Others**	Free search hours plus 100 free pages

https://userfees.fda.gov/OA_HTML/irecPortal.html

https://userfees.fda.gov/OA_HTML/irecLogin.jsp.

User Fees Helpdesk at **userfees@fda.gov.**

https://www.fda.gov/regulatory-information/freedom-information/foia-fees

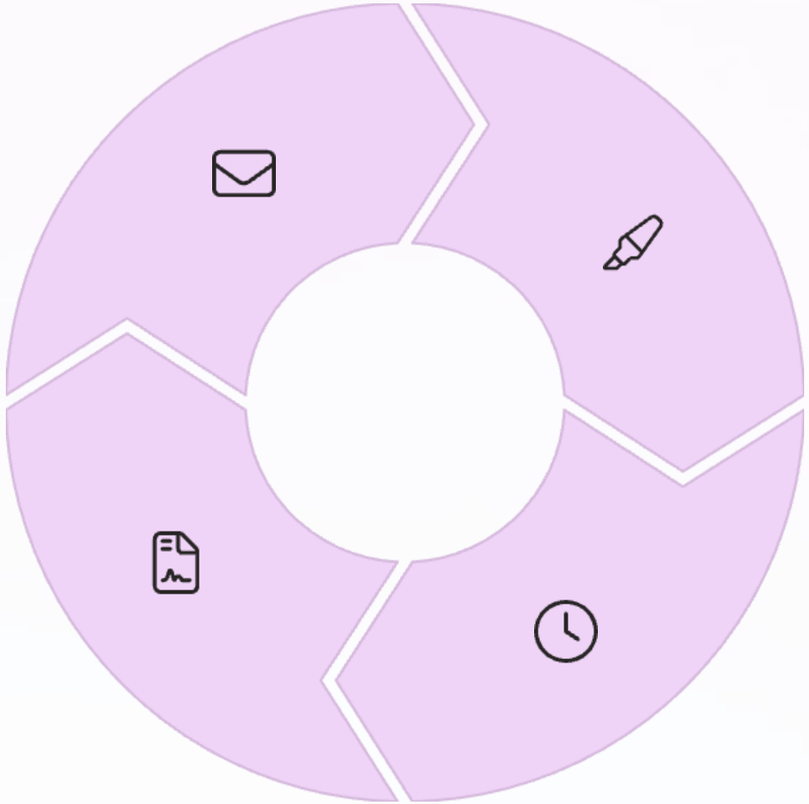
Pre-Disclosure Notification (PDN)

FDA Sends PDN Package

Notification of intent to disclose

Company Reviews & Marks

Identify confidential information



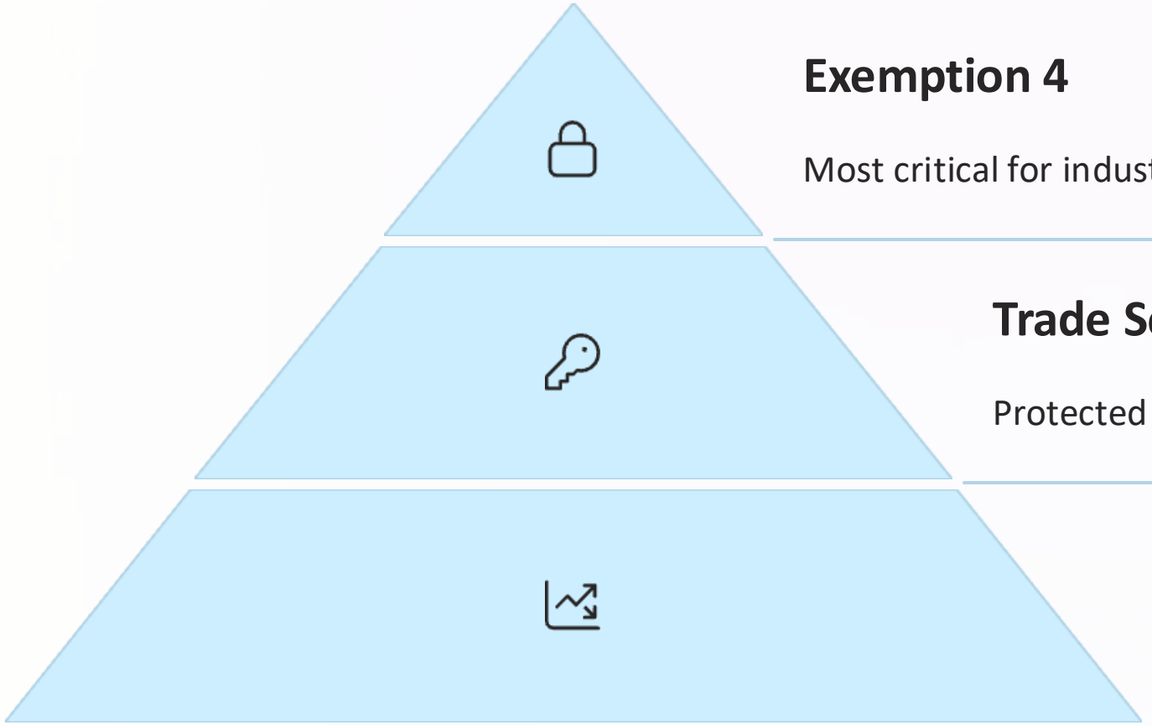
Default Action

FDA applies standard redactions if no response

Response Window

Limited time before FDA proceeds

FOIA Exemptions



Exemption 4

Most critical for industry

Trade Secrets

Protected proprietary information

Commercial Information

Confidential business data

FOIA includes nine total exemptions, but Exemption 4 is most relevant to the medical device industry. This protects trade secrets and secrets and confidential commercial information from public disclosure.

FOIA Processing Timeframes

2-4

Weeks

Processing time for simple requests

18-24

Months

Typical timeline for complex requests like 510(k)s and PMAs

9

Exemptions

Categories of protected information

Remember that FOIA doesn't create new documents. You can only request existing records. Contact CDRH FOIA office for status updates on pending updates on pending requests.


THANK YOU