

***Rocking the Docket:
What on Earth is Dockets
Management and What
do they do?***

The Division of Dockets Management is under the FDA's office of the Commissioner, Office of the Executive Secretary.

We service private industry, individual stakeholders, all of the FDA's regulatory centers, and 15000+ personnel.

***FROM DRUGS TO LASER BEAMS,
WE PROCESS IT ALL!***

FDA – OC – OES - DDM

- The Division of Dockets Management is made up of three teams.
- The Administrative Proceedings Management Team (APMT), The Dockets and Document Management Team (D&D), and the Project and Public Reading Room (P_PRR).

DDM/APMT

- The Administrative Proceedings Management Team handles the bulk of external contact.
- Petitions to the government (Citizen Petitions, Laser Variance Applications etc.)
- Petition and other document comment management
- Federal Register related activities.
- Administrative Records Requests and Freedom of Information Act Requests

How Can We Help You?

- If it involves an administrative decision or will result in a regulatory change or clarification it will at some point involve Dockets Management. We house all of the Agency's records of Administrative Decisions.
- Most commonly, our services to industry involve Records Requests (FOIA), Citizen Petition Processing, and Public Comment Management.

RECORDS

Docket Management Houses All FDA Administrative records and other records going back to the 1950s.

Rule of thumb: If you see it in the Federal Register and it has a FDA Docket Number we likely have the record.

Most records requests are handled very quickly.....

Citizen Petitions

- Citizen Petitions are the mechanism by which a person or organization may request agency administrative action. - Reference listed drug identities are a great example.
- Dockets Management will happily guide all submitters to ensure that they can adhere to format and content requirements for petitions.



Citizen Petitions

Regulations

- 21 CFR 10.20
- 21 CFR 10.30
- *And others...*

Content

- Action Requested
- Statement of Grounds
- Environmental Impact
- Economic Impact
- Certification



Comment Management

Whenever a Citizen Petition has been submitted, the public may provide their opinion.

Whenever the Agency releases a Guidance, Notice, or Final Rule, the public may have their say.

The Division of Dockets Management assists the public in their effort to be heard, we then use our resources to aid the Centers in compiling the various opinions that have been received.

Last Year, Dockets Management Processed over 100,000 documents, each generating uncountable public interest, from one comment to thousands depending upon the issue.



Where do I go for answers about submissions to dockets?

Get to know us!



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- Believe it or not.....You can have our PHONE NUMBER!

The Division of Dockets
Management

(240) 402-7500



Any
Questions.....

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