Guidance for Industry: A Suggested Approach to Resolving Least Burdensome Issues

The 21st Century Cures Act (Cures), signed into law on December 13, 2016, amended several sections of the Federal Food, Drug, and Cosmetic Act. This guidance was developed and issued prior to the enactment of Cures, and certain sections of this guidance may no longer be current as a result. FDA is assessing how to revise this guidance to represent our current thinking on this topic. For more information please contact **CDRH-Cures@fda.hhs.gov (mailto:CDRH-Cures@fda.hhs.gov)**.

PDF Printer Version
ads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073704.pdf)

Document issued on: September 11, 2000

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Program Operations Staff
Office of Device Evaulation
Center for Devices and Radiological Health

Preface

This document intended to be used by the regulated industry if a manufacturer believes that the Least Burdensome (LB) approach to resolving a regulatory issue has not been used. While the approach to resolving LB issues discussed in this document is the suggested approach, a manufacturer may choose alternative approaches, as appropriate.

Public Comment:

Comments and suggestions may be submitted at any time for Agency consideration to Thinh Nguyen, Office of Device Evaluation, HFZ-402, 9200 Corporate Blvd, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Thinh Nguyen, at (240) 276-4010.

Additional Copies:

Additional copies are available from the Internet. You may also send an e-mail request to **CDRH-Guidance@fda.hhs.gov (mailto:CDRH-Guidance@fda.hhs.gov)** to receive a copy of the guidance. Please use the document number 1188 to identify the guidance you are requesting.

Guidance[1] for Industry
A Suggested Approach to Resolving Least Burdensome Issues

As indicated in all recent Office of Device Evaluation (ODE) deficiency letters and guidance documents, we are carefully considering the relevant statutory criteria when we develop these two types of Agency correspondence. We are also making a concerted effort to consider the regulatory and scientific burden that would be incurred in responding to the deficiencies or following our guidance documents. If, upon review, you believe that any deficiency or aspect of a guidance document poses an inappropriate burden (i.e., information is being requested that is not relevant to the regulatory decision) or that there is a less burdensome manner in which to address the issues, you should first contact management in the appropriate review division. This will generally be the branch chief, but may involve a Division Director or a Deputy Division Director. In all cases, division management will make every effort to work with you to identify the least burdensome approach to resolving the issue in question.

If, after speaking with division management, you continue to believe that the requested information does not represent the least burdensome means of addressing a regulatory issue, you should contact the Program Operations Staff (POS) at (301) 594-1190. The appropriate section chief (510(k), IDE/HDE, PMA) within POS will advise you on how to resolve the issues as expeditiously as possible. This may result in further informal reconsideration of the issues at the division level or a recommendation to file a formal appeal under 21 CFR 10.75. Under this section of the regulation, your appeal would be directed to the Office of the Director, ODE for resolution. Please see Section 10.75 for information on submitting a request for internal agency review of an issue.

The above appeal mechanisms track the Office's supervisory structure. If you continue to believe that your concerns have not been satisfactorily resolved, you may choose to **contact the Center for Devices and Radiological Health's Ombudsman (/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOmbudsman/default.htm)**, Mr. David Buckles. Mr. Buckles' responsibilities include facilitating the resolution of least burdensome issues, and he may be reached at (301) 796-5447.

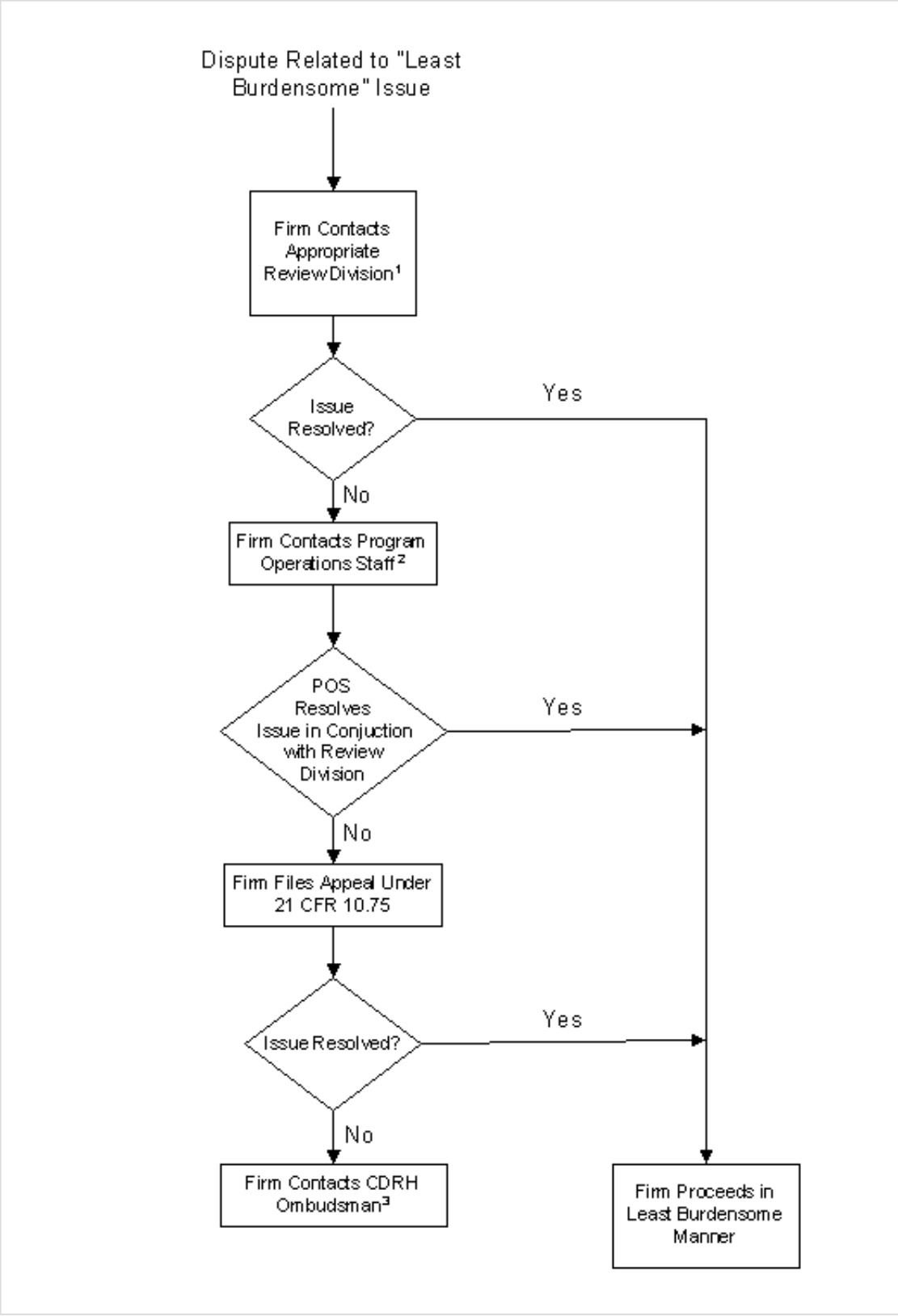
While the suggested pathway to appeal an issue would generally include discussions with ODE management, you may contact the Center's Ombudsman directly, rather than pursuing your concerns within the Office. Mr. Buckles is available to help resolve your concerns in whatever manner you feel most comfortable.

The suggested approach to resolving Least Burdensome issues, as discussed above, is presented graphically on the following page.

---

[1]This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Resolution of a Dispute Related to a "Least Burdensome" Issue



1. Contact begins with the branch chief, but may involve senior level division management.
2. Contact begins with appropriate section chief, i.e., PMA, 510(k) or IDE/HDE.
3. The CDRH Ombudsman may be contacted at any time during this process.

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)