



Attachment 1: Initiation Memorandum Template

Public Health Service

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Memorandum

INITIATION MEMORANDUM

Date: < date of memo >
From: < Initiator(s) >
< Organizational Unit(s) >
To: The File
Cc: CDRH Ombudsman
Subject: < Subject of dispute including relevant file numbers >

Executive Summary

< a summary statement of the position with which the Initiator disagrees >

Issues in Dispute

< description of Initiator's views and how they differ from proposed decision or action, including efforts made to resolve dispute prior to submission of Initiation Memo >

Impact

< an assessment of the consequences if the Initiator's position is not adopted, ex: negative impact on public health, or deviation from current Center practice >

Summary

< a concluding statement of action(s) requested by Initiator >

< *Signature(s) of Initiator(s)* >

References

< include copies of, or links to, relevant documents such as literature articles, standards, guidance documents >