

# CPG Sec. 160.200 FDA Use of Income Tax Information from IRS in Compliance Activity

## BACKGROUND:

The Food and Drug Administration has used income tax information from the Internal Revenue Service in the past to aid the agency's investigative efforts.

## POLICY:

The policy of the agency is that such usage will not be routine. The need for such information will, under all circumstances, be referred to the Associate Commissioner for Regulatory Affairs for a final determination.

If income tax information or actual tax returns are received from the IRS, all such information will be treated as confidential. The physical location of all such information as well as persons who have access to it will be reported to the Associate Commissioner for Regulatory Affairs who will approve these arrangements.

\*Any request for information FDA obtained from IRS should be referred to IRS for response. Privacy Act considerations are covered under 21 CFR 21.1 and 21.10.\*

\*Material between asterisks is new or revised\*

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