CPG Sec. 400.100 Drugs, Human - Failure to Register

BACKGROUND:

Sections 510(b)&(c) of the Act requires the registration of all producers of drugs and devices. When the legislation amending the Act was passed, Congress found and declared that in order to make the regulation of interstate commerce in drugs effective, it was necessary to provide for the registration and inspection of all establishments in which drugs were manufactured, prepared, propagated, compounded, or processed; as the products of such establishments were likely to enter interstate commerce; and that the regulation of interstate commerce in drugs without provision for registration and inspection of establishments engaged only intrastate commerce of drugs would discriminate against and depress interstate commerce of such drugs, and adversely burden, obstruct, and affect such interstate commerce. Section 510(h) requires that each registrant be inspected for compliance every two years.

REGULATORY ACTION GUIDANCE:

If an establishment is required to register and has failed to do so, then every reasonable effort should be made to convince management to register the establishment on a voluntary basis during the initial inspection. If this effort is unsuccessful then an informal discussion between the appropriate Division Director within the Office of Pharmaceutical Quality Operations and the establishment's management should be held. If registration is not accomplished after these initial steps then the issuance of a *warning* letter will be considered by the *CDER*.

Material between asterisks is new or revised

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