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# 21 U.S. Code § 356i

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## Prompt reports of marketing status

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### **(a) Notification of withdrawal**

The holder of an application approved under subsection (c) or (j) of section 355 of this title or subsection (a) or (k) of section 262 of title 42 shall notify the Secretary in writing 180 days prior to withdrawing the approved drug from sale, or if 180 days is not practicable as soon as practicable but not later than the date of withdrawal. The holder shall include with such notice the—

- (1) National Drug Code;
- (2) identity of the drug by established name (or, in the case of a biological product, the proper name) and by proprietary name, if any;
- (3) new drug application number, abbreviated application number, or biologics license application number;
- (4) strength of the drug;
- (5) date on which the drug is expected to no longer be available for sale; and
- (6) reason for withdrawal of the drug.

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