

Drug Application File

Provides Information on NDA, ANDA, or BLA Status

In July 2007, the Centers for Medicare and Medicaid Services (CMS) declared that the presence of an Abbreviated New Drug Application would be used for determining generic status and co-payments within Medicare Part D prescription drug programs. The Drug Application File was created for use by health care organizations involved in the processing of Medicare Part D prescriptions. By providing the FDA-based data as a part of your regular file delivery, Medi-Span® simplifies your maintenance of this data set.

MEETS PAYERS' NEEDS

- **Provides** the most up-to-date application status information with your regular file delivery
- **Provides** manufacturer reported data in situations where status is not yet posted on the FDA site or if the information reported by the manufacturer is different than what is posted by FDA
- **Associates** FDA data to Medi-Span® data
- **Allows** application status updates and Medi-Span® drug file updates to occur on the same frequency



Drug Application File

INCLUDES:

- Application Type
- Application Number
- FDA Approval Date
- In Medi-Span® Database Flag
- Manufacturer-reported information when provided to Medi-Span® in advance of the FDA's website postings
- Medi-Span® Inactive Date
- Reference Listed Drug Flag
- FDA Therapeutic Equivalence Code
- FDA Approval Date Prior to 1/1/1982 Flag
- Manufacturer Reported Application Number*
- Manufacturer Reported Approval Date*
- Application Status Summary File

BENEFITS

- ***Simplifies Application Status maintenance activities***
- ***Ensures timely information is available***
- ***Enables manufacturer reported information to be available in advance of FDA site updates***
- ***Shields from unannounced file layout changes and non-routine postings by the FDA***
- ***Simplifies Application Status analysis***

*Not available for all NDCs



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