One-Time Report on Marketing Status Required by FDARA

The FDA Reauthorization Act of 2017 (FDARA), enacted on August 18, 2017, added section 506I to the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 506I imposes certain reporting requirements on new drug application (NDA) and abbreviated new drug application (ANDA) holders regarding the marketing status of approved products, including a one-time marketing status report.

Under section 506I(c) of the FD&C Act, all NDA and ANDA holders are to review information published in FDA's publication, *Approved Drug Products With Therapeutic Equivalence Evaluations* (the **Orange Book (https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm)**), and submit a one-time written report to FDA indicating that:

1. the NDA or ANDA holder's drug(s) in the active section of the Orange Book are available for sale; or
2. one or more of the NDA or ANDA holder's drugs in the active section of the Orange Book have been withdrawn from sale or have never been available for sale.

Section 506I(c) of the FD&C Act requires that this one-time marketing status report be submitted to the FDA within 180 days of enactment of FDARA (i.e., by ***Wednesday, February 14, 2018***). Here is information on how NDA and ANDA holders can submit this information to FDA:

- The NDA or ANDA holder can submit the one-time report to FDA by letter to each applicable NDA or ANDA file (i.e., each NDA or ANDA listed in the active section of the Orange Book that is covered by such one-time report) through the electronic submissions gateway as part of a single grouped submission. In other words, the same report could be submitted to each applicable NDA and ANDA file as part of a single grouped submission. Please prominently identify the submission as "**MARKETING STATUS REPORT / ONE-TIME UPDATE**."
- In the letter, indicate whether:
  - all of the NDA or ANDA holder's drugs in the active section of the Orange Book are available for sale; or
  - one or more of the NDA or ANDA holder's drugs in the active section of the Orange Book have been withdrawn from sale or have never been available for sale.
- If ***all*** of the NDA or ANDA holder's drugs in the active section of the Orange Book are available for sale, please include a statement in the one-time report confirming that you have reviewed the information published in the Orange Book and that all of your drug products in the active section of the Orange Book are available for sale. As noted above, please submit the one-time report to each NDA or ANDA file covering drug products listed in the active section of the Orange Book.
- If one or more of the NDA or ANDA holder's drug products listed in the active section of the Orange Book have been withdrawn from sale or have never been available for sale, the report should include the following:
  - For drug products that have been withdrawn from sale, include:
    - National Drug Code;

- Established name of the drug;
- Proprietary name of the drug, if applicable;
- NDA or ANDA number for the drug;
- Strength of the drug;
- Date on which the drug is expected to no longer be available, or was no longer available for sale; and
- Reason(s) for the withdrawal from sale of the drug.

- For drug products that have never been available for sale, include:
  - Established name of the drug;
  - Proprietary name of the drug, if applicable;
  - NDA or ANDA number for the drug;
  - Strength of the drug;
  - Date on which the drug will be available for sale, if known and applicable; and
  - Reason(s) for not marketing the drug after approval.
- For the NDA or ANDA holder's other drug products listed in the active section of the Orange Book that are available for sale, please include a statement in the one-time report confirming that you have reviewed the information published in the Orange Book and that all of your other drug products in the active section of the Orange Book are available for sale. As noted above, please submit the one-time report to each applicable NDA or ANDA file through the electronic submissions gateway as part of a single grouped submission, including to each NDA or ANDA file covering drug products listed in the active section of the Orange Book that are available for sale.

In you have questions regarding the information described above, please send them to the Orange Book staff at **orangebook@fda.hhs.gov (mailto:orangebook@fda.hhs.gov)**.

More in Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) (/Drugs/InformationOnDrugs/ApprovedDrugs/ApprovedDrugProductswithTherapeuticEquivalenceEvaluationsOrangeBook/

Orange Book FR Safety or Effectiveness Determinations List (/Drugs/InformationOnDrugs/ApprovedDrugs/ApprovedDrugProductswithTherapeuticEquivalenceEvaluationsOrangeBook/