

# US Department of Health and Human Services

## Privacy Impact Assessment

**Date Signed:**

02/12/2014

**OPDIV:**

FDA

**Name:**

Orange Book System

**PIA Unique Identifier:**

P-5635178-944502

**The subject of this PIA is which of the following?**

Major Application

**Identify the Enterprise Performance Lifecycle Phase of the system.**

Operations and Maintenance

**Is this a FISMA-Reportable system?**

Yes

**Does the system include a Website or online application available to and for the use of the general public?**

No

**Identify the operator.**

Agency

**Is this a new or existing system?**

New

**Does the system have Security Authorization (SA)?**

No

**Indicate the following reason(s) for updating this PIA.****Describe the purpose of the system.**

The purpose of the Orange Book (OB) System is to automate both the workflow of the OB staff and the OB interface with other Center for Drug Evaluation and Research (CDER) systems as well as CDER's Office of Communication (OCOMM), the office which manages the OB application.

The OB system also serves to fulfill a mandate of the Federal Food, Drug, and Cosmetic Act (FD&C Act). That mandate requires that FDA publicly list drug products approved under section 505 of the FD&C Act, as well as drug substitutability information with respect to generic drug products and brand name products at the pharmacy level. There is a broad spectrum of users of the Orange Book from the Agency, other government agencies, the public, and industry.

The OB system streamlines data entry and eliminates the numerous manual steps previously required to prepare the Orange Book. It will: allow for changes and updates to established product records, including updating any necessary patent information; produce reports regarding new drug applications on a daily, monthly, quarterly, and/or annually basis; and, allow system administrators to make administrative changes to the system (i.e., updating the name or address of a manufacturing firm).

**Describe the type of information the system will collect, maintain (store), or share.**

The OB system contains data regarding: New Drug Application (NDA) approvals in the month they were approved; discontinued products; patent information, including patent exclusivity information; pharmacological information about a drug, and the manufacturer's firm name and address.

**Provide an overview of the system and describe the information it will collect, maintain (store), or share,**

The OB system is the subsystem of the Drug Product Reference File (DPRF) that houses product information for approved generic drug applications. This data in OB is updated daily.

The Orange Book is particularly critical in determining when generic drug versions can be substituted for the brand name product. Generic drugs now represent more than 80 percent of drugs dispensed in the United States. Although some outside users repackage the information available via OB, the system is the only definitive source for Therapeutic Equivalence and Reference Listed Drug data, as well as Patent and Exclusivity data.

OB supplies information (through CDER's Office of Communication) to a publicly available online directory of FDA-approved drugs. It contains information on several different types of drug products including products that are currently marketed, products that have been approved but not marketed, products that have been discontinued, products that have had approvals withdrawn for reasons other than safety or efficacy, products that are designated for export only, and products that are for use by the military.

For each product, OB maintains information regarding the approved New Drug Application or Abbreviated New Drug Application, all product changes, and patent and exclusivity information.

The database is updated daily for generic drug approvals and monthly for NDA approvals. OB sends this data to CDER's OCOMM, through which it is published to a web-based interface with [fda.gov](http://fda.gov).

**Does the system collect, maintain, use or share PII?**

No