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Center for Drug Evaluation and Research
Division of Drug Information
Via: orangebook@fda.hhs.gov

October 3, 2024

Dear Sir or Madam,

Knowledge Ecology International (KEI) requests that the Food and Drug Administration (FDA) publish all historical data from the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) on its public website. This information is important for researchers and policymakers as they consider patent ownership issues and ways to improve the management of knowledge resources.

Currently, the version of the Orange Book available on the FDA website only includes unexpired patents. When KEI has requested earlier data from the Orange Book, we have been directed to submit a Freedom of Information Act (FOIA) request to obtain this data. This leads to research delays and keeps the information unavailable to the broader public. As a nonprofit research and advocacy organization, KEI has published the Orange Book Data that we have obtained via FOIA,[1] but regularly updating this information via FOIA requests causes significant lags in updated data. For example, KEI filed a FOIA request on September 7, 2023 to update our database to include the Orange Book data from 2018 to 2023. We have yet to receive a complete response to that request.[2] Additionally, the information would be more widely consumed if available directly from the FDA.

KEI notes that the FDA Orange Book website states that “Over time, there will be an archive for the annuals and each year's December Cumulative Supplement.”[3] When will this be available?

The historical data in the Orange Book is very important for addressing a number of critical areas of research. For example:

[1] https://drugdatabase.info/fda-orange-book-patents/
[2] We received a partial response in August 2024, following an email by KEI requesting an update on the status of the request.
[3] https://www.fda.gov/drugs/drug-approvals-and-databases/frequently-asked-questions-orange-book

1. Over time, how many FDA-approved products have one or more patents in the Orange Book that have disclosed (or should have disclosed) federal rights in the patented invention, and which funding agencies were involved?
2. Over time, how many and what type of patents end up in the Orange Book for specific products, and how does this change over the time period that a product is on the market?
3. How does the number of patents in the Orange Book relate to product revenues or the time for generics to enter the market?

Additionally, the government is currently finalizing a “Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights” which pertains to treatments in which the government has rights in the patents. The NIH is considering a new policy of requiring licensees to adopt access plans, and one issue concerns the leverage the NIH will have, when patent landscapes are complex. In cases such as these, looking at historical data is useful.

We assume that the FDA has in machine readable format all historical data on FDA Orange Book patents. KEI requests a meeting to discuss this issue with you further and to highlight the utility and importance of publishing this data. Thank you in advance for your attention to this issue.

Sincerely,

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Knowledge Ecology International