The IID – A Historical Industry Perspective and Alternative Options for the Future

GPhA
Generic Pharmaceutical Association

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April 28 2015

Overview of the presentation

- *What is the IID?*
- *How the IID discussion started*
- *Past process*
- *Current process*
- *Future opportunities – Improvements and Enhancements*
- *Outcome*
- *Summary*

What is the IID?

- *The Inactive Ingredients Database (IID) is an FDA database that lists inactive ingredients.*
- *The IID only provides a list of inactive ingredients that have been approved in an NDA or ANDA drug product formulation by the FDA.*
- *Once an inactive ingredient has appeared in an approved drug product for a particular route of administration and dosage form, it is not considered new and may require a less extensive review in a new drug product.*

How did the IID discussion start?

- *Fall of 2011 –*
  - *Formation of OGD IID Working Group*
  - *Data discrepancies*
  - *UNII Numbers and the Substance Registration System (SRS) Team*
  - *IPEC-Americas – 12/2011 - initial meeting*
  - *OGD/IPEC-Americas Working Group*
- *Winter of 2011 to 2012 –*
  - *Data integrity*
    - *Completeness*
    - *Accuracy*
    - *Misrepresentation*

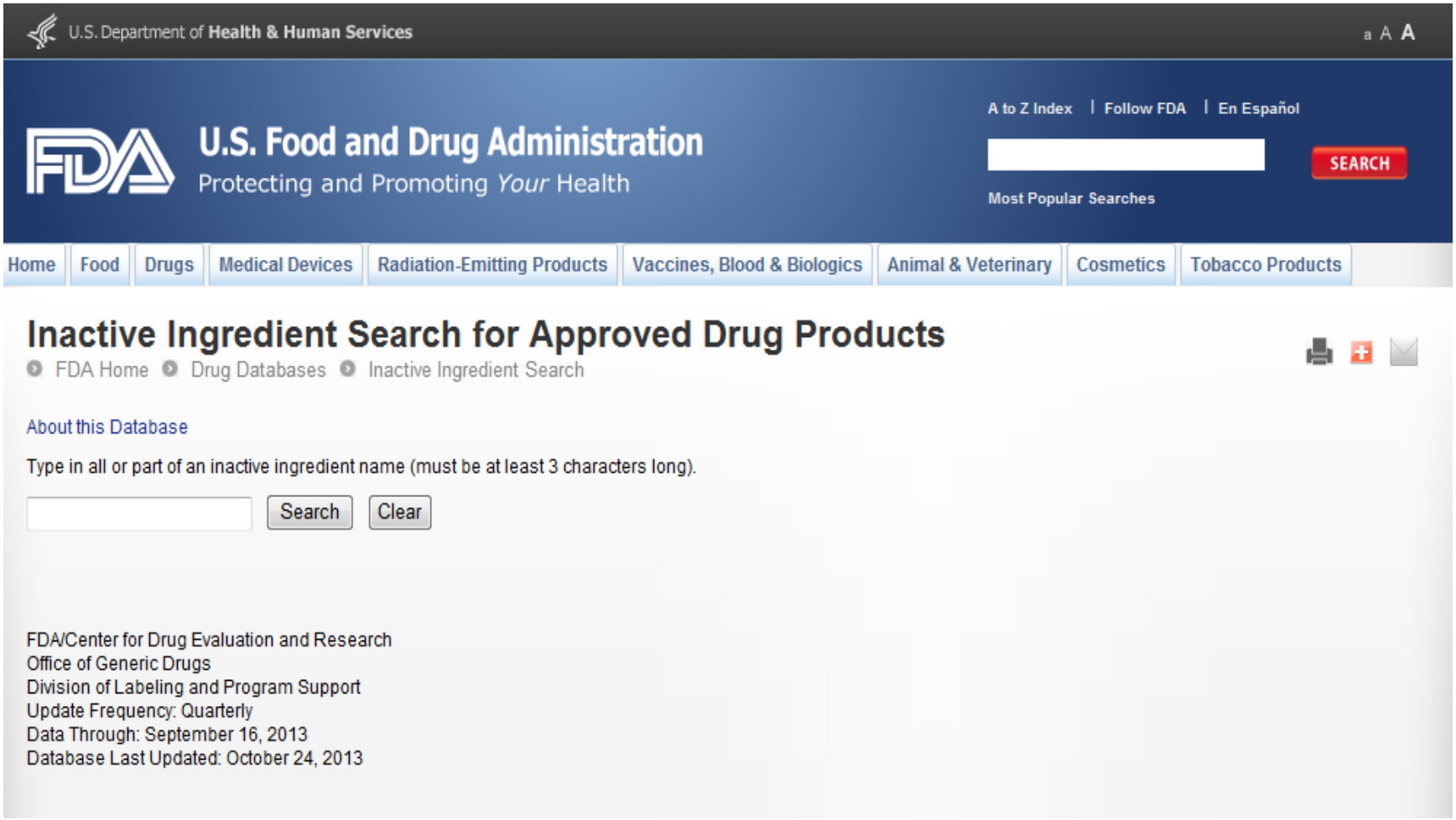
Past process

- *Data entry into the Drug Product Reference File – aka DPRF*
  - *Office of Business Informatics*
  - *Data entry quality controls*
- *DPRF interface with the IID*
  - *Office of Generic Drugs - Orange Book*

Current Process

- *Generic Drug User Fee Amendments (GDUFA)*
  - *New IT platform: Integrity*
    - *Office of Business Informatics*
    - *Data entry quality controls*
  - *Data integrity*
    - *Completeness*
    - *Accuracy*
    - *Misrepresentation*

The IID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Inactive Ingredient Search for Approved Drug Products
FDA Home Drug Databases Inactive Ingredient Search
About this Database
Type in all or part of an inactive ingredient name (must be at least 3 characters long).
Search
Clear
FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency: Quarterly
Data Through: September 16, 2013
Database Last Updated: October 24, 2013

Future opportunities – Improvements and Enhancements

Improvements:

- *Complete*
- *Accurate*
- *More representative*

Enhancements:

- *Maximum daily intake*
- *Searchable functionality*
- *Provision for including a listing for common, generic, compendia, cosmetic, brand and trade names, as well as any other synonyms for inactive ingredients*
- *Family ties*

Outcomes

Agency

- *Efficient, consistent and timely reviews*
- *Workload management*
  - *Technical review process*
  - *Controlled correspondence*
- *GDUFA metrics*

Industry

- *Achieve Agency quality standards*
- *Increase innovation in product design*
- *Workload management*
  - *Controlled correspondence*
- *Decrease uncertainty*

Summary

The Agency must:

- *Look beyond the capabilities of what can be done within CDER and the Agency.*
- *Explore other viable options to address the needs of the Agency and industry.*
- *Act now.*

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Thank You