U.S. FOOD & DRUG ADMINISTRATION

FDA Update
The National Drug Code

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- Background
- Drug Listing
- National Drug Code (NDC)
- NDC Directory
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- Summary

Background

- Establishment Registration
  - Statutory requirement since 1963
  - 21 U.S.C. 360(b), (c), (d), and (i)
- Drug Listing
  - Statutory requirement since 1973
  - 21 U.S.C. 360(j)(1)

Background

- Registration and listing information was historically submitted by firms using paper forms (2656, 2657, 2658)
- Starting June 1, 2009 FDA stopped accepting the paper forms
- Per 21 CFR 207.61, information must be submitted to FDA in electronic format
  - Structured Product Labeling (SPL)
    - Document markup standard adopted by FDA as mechanism for exchanging product and facility information

Drug Listing

- All registered establishments must list all drugs they produce for U.S. commercial distribution under their own labeler code. This includes active pharmaceutical ingredient manufacturers, other bulk drug manufacturers, contract manufacturers, repackers, and relabelers
- Initial drug listings should be submitted within three days after initial registration of the establishment

Drug Listing

- Listing data must be reviewed twice a year
  - Updates must be made no later than June or December following a change in the information (21 CFR 207.57(b))
- Listings with no changes must be certified annually between October – December
- Listings not updated or certified will be inactivated

National Drug Code (NDC)

- Current NDC Formats
  - Unique 10-digit, three-segment number
  - Three NDC configurations:
    - 4-4-2
    - 5-3-2
    - 5-4-1

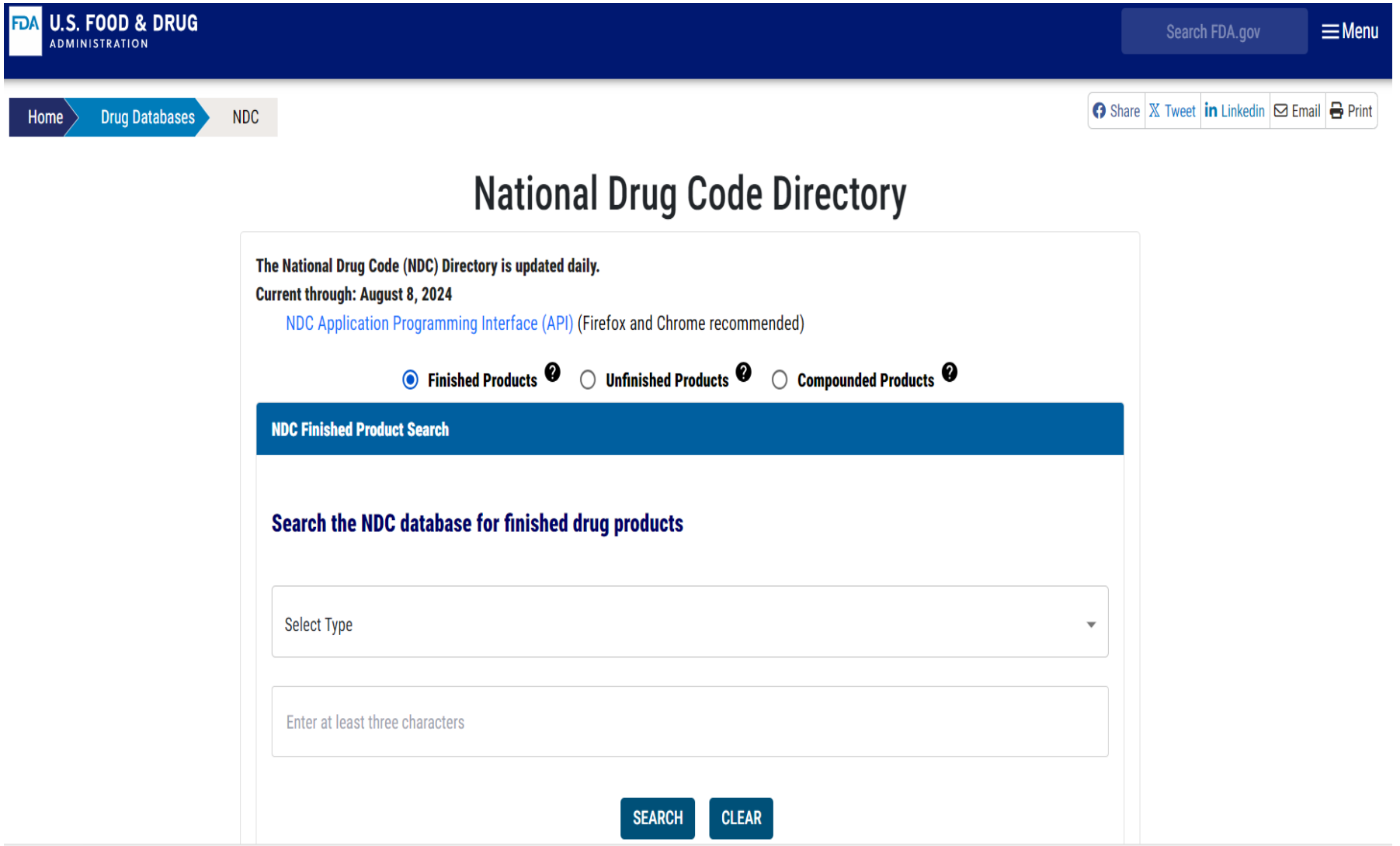
National Drug Code (NDC)

- Unique identifier for drugs in U.S. commercial distribution
- Labeler code (55555-555-55)
  - The first 4 or 5 numeric characters of the 10-digit code identify the manufacturer or distributor
  - Assigned by FDA
- Product code (55555-555-55)
  - Identifies the drug formulation
    - Must be different for different formulations (e.g., strength, characteristics, etc.)
- Package Code (55555-555-55)
  - Identifies the trade package size and type
    - Assigned by the manufacturer or distributor before drug listing for FDA evaluation

Future Format NDC

- Proposed Rule on the Future NDC Format
  - FDA has about 10-15 years of available 5-digit labeler codes
  - Currently, HIPAA requires an eleven-digit NDCs (requiring a lead “0” to be added to the labeler, product, or package code to create a 5-4-2 format) and this can cause confusion with the FDA ten-digit requirement
  - Proposed moving to a six-digit labeler code and twelve-digit NDC
  - Proposed universal NDC configuration:
    - 6-4-2

National Drug Code Directory | FDA



NDC Directory

- FDA publishes the listed NDC numbers as part of the listing information in the NDC Directory
- Contains ONLY information submitted to FDA by labelers
- Searchable function for “finished” and “unfinished” drug products
- Excel files available for download
- Updates daily (Monday to Friday)

NDC Directory

- Final marketed drugs:
  - Rx and OTC Drugs
  - Approved
    - ANDAs, NDAs, and BLAs
  - Unapproved
    - Homeopathic, Medical Gases, Other
- Unfinished drugs
  - Active pharmaceutical ingredients (APIs)
  - Drugs for further processing
  - Drugs exclusively manufactured for PLDs
- Compounded drugs
- Not published
  - Animal drugs
  - Blood related products

NDC Directory

- Inclusion does not indicate that FDA has verified the information provided or that the products are FDA approved
- Assignment of an NDC number does not in any way denote FDA approval of the product
- Inclusion does not mean a product is covered or eligible for reimbursement by Medicare, Medicaid, or other payers
- Assignment of NDC number to non-drug products is prohibited

Other NDC Publications

- DailyMed (nih.gov)
- Drugs@FDA: FDA-Approved Drugs
- FDA Label Search
- NSDE | FDA
- Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations (fda.gov)

Summary

- NDCs are unique identifiers for drug products in the U.S.
- All drug products in U.S. commercial distribution must be assigned an NDC
- The NDC is a “smart” number with distinct segments
- Drug listings are published in the NDC Directory and numerous other websites

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Questions

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Thank You


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