



# Feedback for FDA staff prior to PDUFA reauthorization

DAVID RIDLEY, PHD

JULY 23, 2020

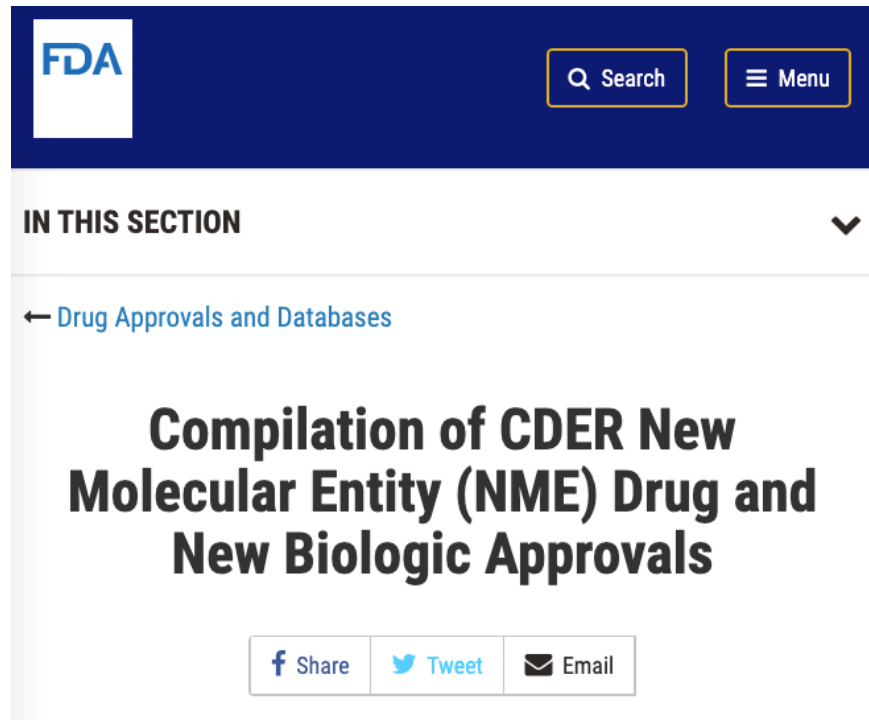
# My Perspective

- ▶ Health economist at Duke University (my own views)
- ▶ Lead author of paper proposing priority review voucher
- ▶ Regular user of FDA data

# Thank You

- ▶ FDA plays a vital role and does it well
- ▶ FDA has managed priority review voucher program well
  - ▶ Program is imperfect but FDA doing its best
  - ▶ Priority reviews have been consistently 6 months
  - ▶ Voucher user fees are sensible (\$2M in 2020, was \$5M in 2012)
  - ▶ Criteria for adding tropical diseases are sensible
- ▶ FDA shares many useful data sets
  - ▶ For example, NME data shared in February 2020
  - ▶ But much more to do on data transparency

# Positive Example: NME Data



The screenshot shows the top navigation bar of the FDA website with the logo, a search box, and a menu button. Below the navigation bar, there is a section titled 'IN THIS SECTION' with a dropdown arrow. A breadcrumb trail shows '← Drug Approvals and Databases'. The main heading is 'Compilation of CDER New Molecular Entity (NME) Drug and New Biologic Approvals'. At the bottom of the heading area, there are three social sharing buttons: 'Share', 'Tweet', and 'Email'.

- ▶ NME & BLA data for 1985 to 2019
- ▶ Excel format
- ▶ Released in February
- ▶ Dr. Kathleen Miller involved



# Negative Example: Shortages Data

CHANGING HEADERS

NO DATA

NO DATA

MISSPELLING

NESTED TABLES

## Methylphenidate HCl

Company	Product	Availability Information	Notes	Reason	Date Updated
Sandoz Customer Service: 1-609-627-8500	5 mg, 100s (NDC 00781-5748-01)	Capacity constraints and receiving API orders	Revised 6/7/2012		
	10 mg, 100s (NDC 00781-5749-01)				
	20 mg, 100s (NDC 00781-5753-01)				
	20 mg, 100s (NDC 00781-5754-01)				
Mallinckrodt Customer Service: (800) 325-8888	5 mg (100s - NDC 00406-1121-01; 1000s - NDC 00406-1121-10) 10 mg (100s - NDC 00406-	All strengths of methylphenidate IR and ER tablets are expected to be available by mid-June to meet historical demand.		Manufacturing delays	Revised 5/18/2012

## Anadrol-50 tablets (Oxymetholone Tablets) (8/1/2011)

Company/Products	Reason	Related Information
Meda Pharmaceuticals Inc.: 732-564-2200  50 mg (bottles of 100) - NDC 68220-055-10	This shortage is due to Active Pharmaceutical Ingredient (API) constraints.	Please check with your wholesaler for available inventory. Meda cannot estimate a release date for additional supplies.

## Aquasol A (updated 9/22/2011)

Company/Products	Reason	Related Information
Hospira Inc. 1-877-946-7747  50,000 units/mL, 2 mL ampule (NDC 61703-418-07)	Change in manufacturing sites.	Hospira anticipates next delivery in 1Q 2012.

## Avandia (rosiglitazone and hydrochlorothiazide) Tablets (2/25/2011)

## Methotrexate Injection

Company	Product	Availability Information	Notes	Reason	Date Updated
APP Customer Service 1-888-386-1300	25 mg/mL; 10 mL vial (NDC 63323-0123-10)	Available		Increased demand	Reverified 5/25/2012

## Sodium Bicarbonate Injection (Initial Posting-3/20/12)

Company/Products	Reason	Related Information	Date Updated
Bedford Customer Service 1-800-562-4797			
Amphastar Pharmaceuticals Inc. Customer Service: 1-800-423-4136	Increased Demand due to competitor backorders	Next release on March 26, 2011 Additional release anticipated on April 5, 2011.	
Sodium Bicarbonate Injection USP, 8.4%, 50 mL Prefilled Syringe NDC: 0548-3352-			
APP 1-888-386-1300 4.2% 2.5 mEq, 5 mL (NDC 63323-0026-05)	Increased demand	APP is currently back-ordered and expects a release late May. Please check wholesalers for inventory.	Reverified 4/24/2012
Hospira, Inc. Customer Service: 1-877-946-7747	Manufacturing delay; Other manufacturer shortages/market withdrawal.	Product 4%; 5 mL vial (NDC 0409-6609-02): next delivery May. Product 0.5 mEq/mL; 10 mL Abboject (NDC 0409-5534-34): next delivery May. Product 0.9 mEq/mL; 50 mL Abboject (NDC 0409-4916-34): next delivery May. Product 1 mEq/mL; 50 mL vial (NDC 0409-6625-02): next delivery April. Product 1 mEq/mL; 50 mL Abboject (NDC 0409-6637-34): next delivery May. Product 1 mEq/mL; 10 mL Abboject (NDC 0409-4900-34): next delivery April.  Please check with your wholesaler for available inventory.	Revised 5/2/2012
4%; 5 mL vial (NDC 0409-6609-02)			
0.5 mEq/mL; 10 mL Abboject (NDC 0409-5534-34)			
0.9 mEq/mL; 50 mL Abboject (NDC 0409-4916-34)			
1 mEq/mL; 50 mL vial (NDC 0409-6625-02)			
1 mEq/mL; 50 mL Abboject (NDC 0409-6637-34)			
1 mEq/mL; 10 mL Abboject (NDC 0409-4900-34)			

Source:  
Jeff Jones &  
David Ridley

# Negative Example: Shortages Data

- ▶ Accessed through (non-gov.) Internet Archive
- ▶ Occasional snapshots with months in between
- ▶ Posted in html format with format changing
- ▶ Inconsistent headers and tables within tables
- ▶ Cannot be read by machines

# Data Transparency: Proposal

- ▶ Post data in a data base, not just html table
- ▶ Post data, even if imperfect, with caveats
- ▶ Create data czar reporting to Commissioner
  - ▶ Evaluated on new data availability



# Data Transparency: Concerns

- ▶ If data errors, could be sued
  - ▶ Response: include caveats and contact info.
  - ▶ Iterative process to refine data that benefits all
- ▶ It's commercially sensitive
  - ▶ Response: much of data has been public but poorly formatted

# Data Transparency: Benefits

- ▶ Benefits FDA
  - ▶ refine data and interact with people that improve it
  - ▶ crowd source assignments from Congress
- ▶ Benefits society
  - ▶ provide information about problems and solutions
  - ▶ example: which companies and drugs have frequent shortages

# Conclusions

- ▶ FDA is doing good work
- ▶ FDA should improve data access & sharing
- ▶ FDA should create a high-level job for data access