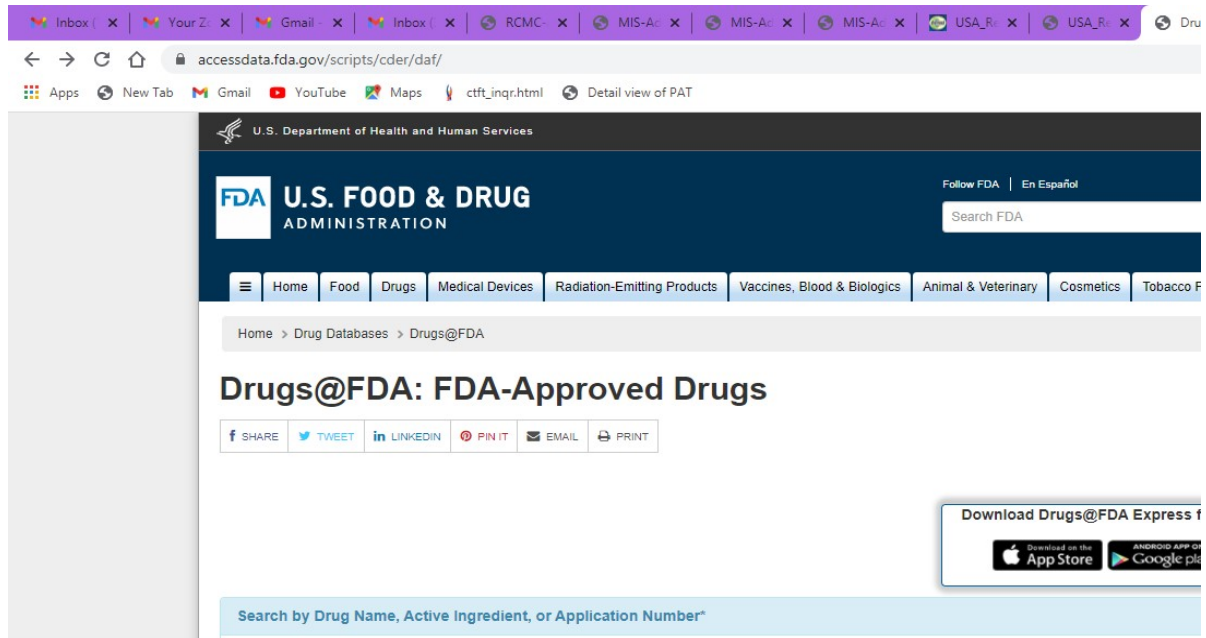


For ANDA Approval products:

<https://www.accessdata.fda.gov/scripts/cder/daf/>.



Enter ANDA Number in the search Button and It will open other page as shown below

The screenshot shows the search results for ANDA 212541. The page is titled "Products on ANDA 212541" and includes a table with columns for Drug Name, Active Ingredients, Strength, Dosage Form/Route, Marketing Status, TE Code, RLD, and RS. The table shows one entry for PYRAZINAMIDE. Below this, there is a section for "Approval Date(s) and History, Letters, Labels, Reviews for ANDA 212541" which includes a table for "Original Approvals or Tentative Approvals". The table has columns for Action Date, Submission, Action Type, Submission Classification, Review Priority; Orphan Status, Letters, Reviews, Labels, Patient Package Insert, and Notes. The first entry in this table has an Action Date of 07/27/2020, which is circled in red. A red arrow points to this date with the text "CONSIDER THIS DATE" below it.

Drug Name	Active Ingredients	Strength	Dosage Form/Route	Marketing Status	TE Code	RLD	RS
PYRAZINAMIDE	PYRAZINAMIDE	500MG	TABLET;ORAL	Prescription	AB	No	No

Action Date	Submission	Action Type	Submission Classification	Review Priority; Orphan Status	Letters, Reviews, Labels, Patient Package Insert	Notes
07/27/2020	ORIG-1	Approval		STANDARD		Label is not available on this site.

CONSIDER THIS DATE

- Action date to be consider as reference date for the approval of ANDA product from FDA and MAI Application to be initiate with this date.
- Financial Year will be consider based on the Action date

DMF Approval / Type – II products: Link shown below:

<https://www.fda.gov/media/85138/download>

After click on this link An Excel sheet will be downloaded as shown below:

- Financial Year will be consider based on the Complete Assessment Review date.
- In this Excel sheet, Complete Assessment Review date to be consider as reference date for the approval of DMF product from FDA and MAI Application to be initiate with this date.

MF User Fee Obligation Report				
				April 16, 2021 2:18:14 PM
Available for Reference Type II DMFs for APIs for Generic Drug Applications				
For questions regarding this list, please email DMFOGD@fda.hhs.gov				
Appl Type/Number	Holder	Subject	Payment Date	Completeness Assessment Review Date
MF 000191	SPEGX LLC	PARZONE BITARTRATE (DIHYDROCODEINE BITARTRATE)	12/4/12	10/24/12
MF 000453	FIS FABBRICA ITALIANA SINTETICI SPA	NITROFURANTOIN & NITROFURANTOIN MACROCRYSTALS	12/21/12	1/18/13
MF 000467	FIS FABBRICA ITALIANA SINTETICI SPA	CHLORDIAZEPOXIDE HCL	10/26/17	11/16/17
MF 000745	CAMBREX PROFARMACO MILANO SRL	CHLORDIAZEPOXIDE HYDROCHLORIDE	4/13/17	11/8/17
MF 000881	CAMBREX PROFARMACO MILANO SRL	HYDROCHLOROTHIAZIDE	12/11/12	1/11/13
MF 000883	CAMBREX PROFARMACO MILANO SRL	CHLOROTHIAZIDE	9/21/20	9/25/20
MF 001076	AJINOMOTO CO INORTH CAROLINA	AMINO ACID PRODUCTS	7/2/18	8/14/18
MF 001166	SIEGFRIED USA LLC	BUTALBITAL USP	12/3/12	11/11/12
MF 001241	FMC LITHIUM SUB FMC CORP	LITHIUM CARBONATE	8/21/18	9/10/18
MF 001356	DOW CHEMICAL CO	CARBOWAX POLYETHYLENE GLYCOL	11/16/12	1/11/13

consider this date

