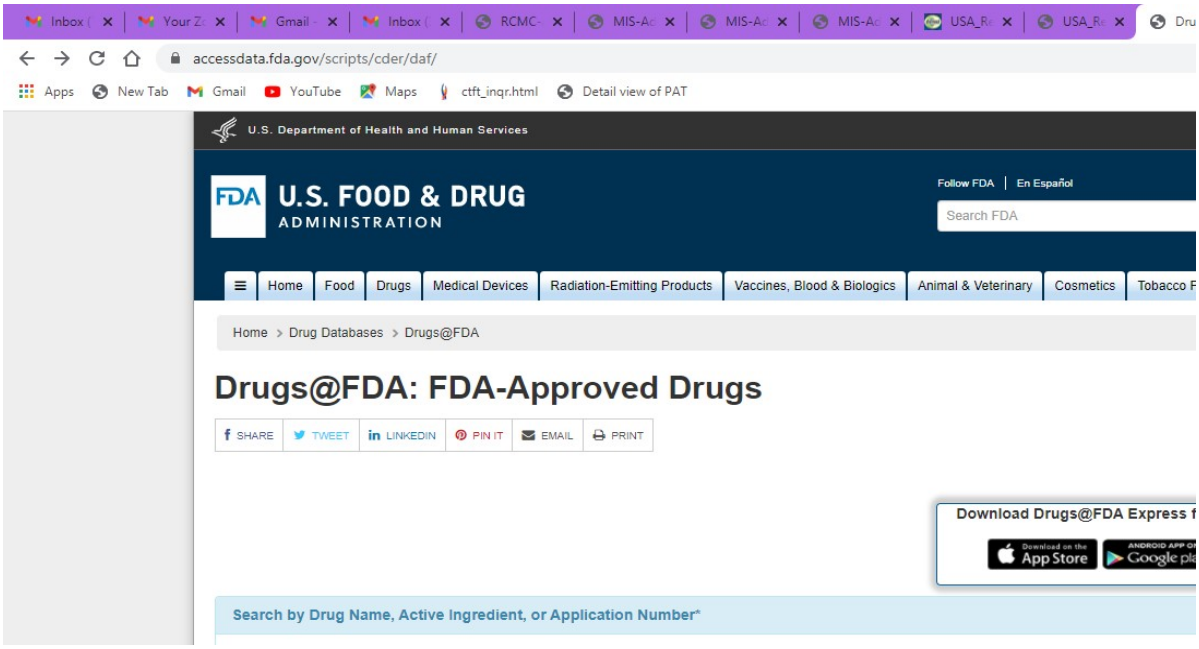
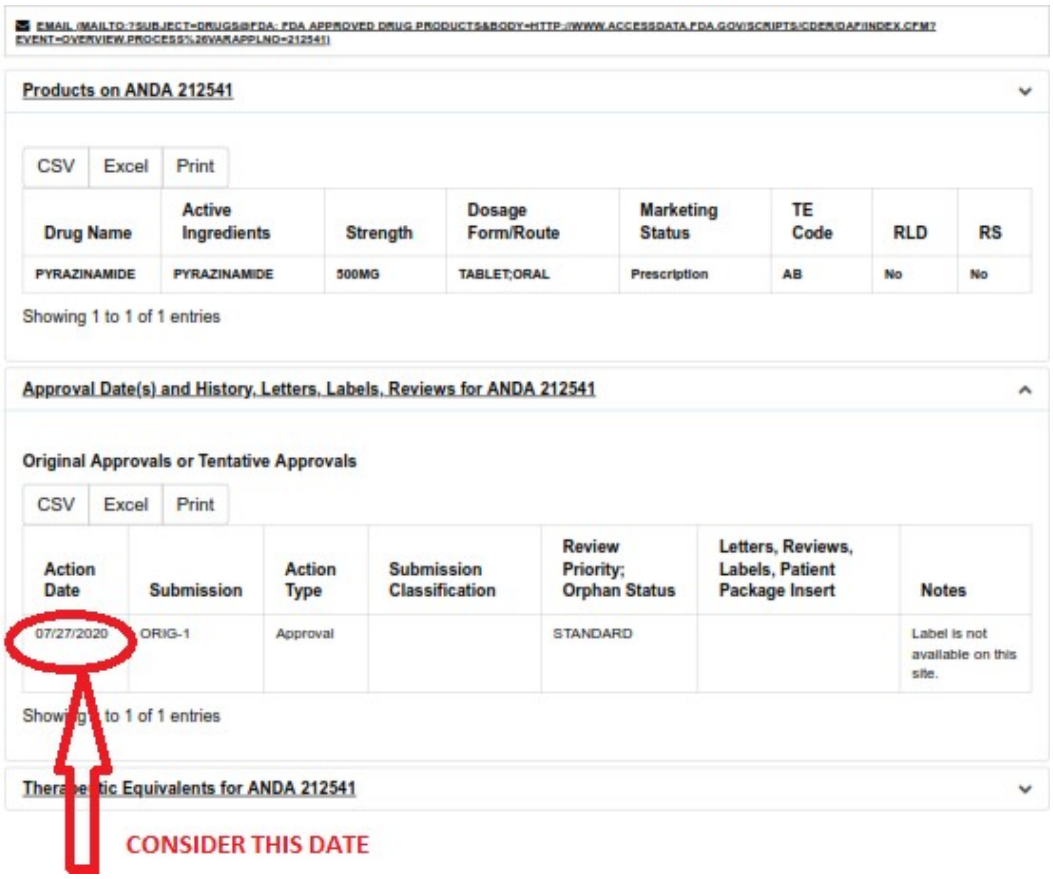
For ANDA Approval products:

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



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



- 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

consider this date

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	SPECGX 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