. **U.S. FOOD & DRUG**

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**FEB** 2 8 2018

Andrew Kolodny, M. D.

Physiciansfor Responsible Opioid Prescribing 12800 Whi1cwater Drive, Suite I**00** Minnetonka\_ MNSS343

Re: Docket No. FDA-2017-P-S396

Dear Dr. Kolodny:

I nm writing 10 inform you that 1he Foodand Drug Administrn1ion(FDA or Agency) hns

not yet resolved the issues raised in your citi7.cn pctili,on docker no. FDA-2017-P-5396.

submiucd on behalfof your organizations and several others. Your pc1ition requests that FDA "immediately scck remov:il of or:il and tmnsmucosa.l [ultra-high dosa.ge unit) opioid analgesics from themarket"(Petition at I ).

FDA has been unable t<> reach odecision on your pc1tiion because it misessignificant issues requiring extensive review and analysis by Agency onicials. This inlerim response is provided in accordance with FDA regulations on citiZ<'ll petitions (2 l Cl' R 10.30(cX2)). \Ve will respond to your petition as soon as we hllve reached adecision on your request.



Carol J. cnneu Deputy Director

Oniceof Rcgula1ory Policy

Center for Drug Evaluationand Research

US **Food** & **D"ug AdmntJUo"°"**

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