From: OC CCP Questions
To: [redacted]
Subject: NIPT approved by FDA?
Date: Monday, November 05, 2018 1:06:26 PM

Good afternoon –

This office does not have the information you are requesting. This is a general OGCP mailbox. You will need to contact others in FDA. Please see a few contacts provided below.

Division of Pediatric and Maternal Health (CDER) at (301) 796-2200

Division of Pediatric and Maternal Health -- About the Center for Drug Evaluation and Research > Division of Pediatric and Maternal Health

Office of Women's Health - Office of Women's Health

Consumer Updates > Pregnancy: A Time for Special Caution

Kind regards,

Doreen M. Kezer, MSN
Senior Health Policy Analyst
Office of Good Clinical Practice
Office of the Commissioner, FDA

This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(k) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: [redacted]
Sent: Monday, November 05, 2018 12:44 PM
To: CDRH Small Manu. Assistance <DSMA@CDRH.FDA.GOV>
Subject: NIPT approved by FDA?

Dear FDA,

Re:
The FDA Warns Against the use of Many Genetic Tests with Unapproved Claims to Predict Patient Response to Specific Medications: FDA Safety Communication.
November 1, 2018
https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm624725.htm?utm_campaign=The%20FDA%20Warns%20Against%20the%20use%20of%20Many%20Genetic%20Tests%20with%20Unapproved%20Claims&utm_medium=email&utm_source=Eloqua&elqTrackId=F8057CB313FF19A3460C4C3710BC5851&elq=6d8ece99d3d04ee287233c1648a00937&elqaid=5704&elqat=1&elqCampaignId=4589

My question:

Is NIPT (Noninvasive Prenatal Testing (A.K.A. cell-free DNA testing)) approved by FDA?

Any FDA document(s) about the approval or non-approval (of NIPT) ?

Regarding NIPT clinical trials, does FDA have any suggestion about NIPT usage, as well as the test/trial sample size and agreement between investigator and participants?

Appreciate having your help ASAP.

Thank you and Regards,
[redacted]