From: OC GCP Questions
To: [redacted]
Subject: Have any investigational new drug applications been filed to pursue human cloning technology
Date: Wednesday, August 01, 2018 10:55:00 AM
Attachments: [redacted]

Good afternoon –

Anything submitted to FDA under an IND is considered confidential. For questions regarding human cloning, we will need to contact the Center for Biologics (CBER). Contacts are below.

Phone: 1-800-835-4709
Fax: 240-402-8010

Email: ocod@fda.hhs.gov

Kind regards,

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

U.S. FOOD & DRUG ADMINISTRATION

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: Tuesday, July 31, 2018 1:15 AM
To: OC GCP Questions <gcpquestions@fda.hhs.gov>
Subject: Have any investigational new drug applications been filed to pursue human cloning technology

Hello,
I have been unable to find any instances where a IND has been submitted to pursue human cloning. I found the 1998 letter that states:
As described more fully below, the appropriate mechanism to pursue a clinical investigation using cloning technology is the submission of an investigational new drug application (IND) to FDA.
https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm150508.htm

Has there been any IND submitted to pursue human cloning?

Thanks,
[redacted]

[redacted]

[redacted]