Food and Drug Administration
Investigational New Drug Regulations
(OMB Control Number 0910-0014)

CHANGE REQUEST (83-C)

FDA is proposing a non-substantive change to Form FDA 1571: Investigational New Drug Application (IND). We are currently proposing to review the form to include the following:

Field 6B:

6B. Select One:	Commercial	☐
	Research	☐

Reason:

Effective May 5, 2018, commercial INDs will be required in electronic (eCTD) format. In preparation for this change, FDA believes an identifier is needed on the collection instrument to ensure efficient and appropriate processing of the submission (i.e., differentiate between a commercial and research IND).

Page 4 of Sections B (Timetable for Implementation of Electronic Submission Requirements) and C (Types of Submissions That Are Exempted From the Electronic Submission Requirement Described in This Guidance Document) of "Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry", a specific guidance under 745a, provides both a timetable for electronic submissions by category.

Table 1: Timetable for the Initial Implementation of the Electronic Submission Requirement

Submission Type	Final eCTD Guidance Published to FDA Web site (yyyy-mm-dd)	Date Requirement Begins (yyyy-mm-dd)
NDA ANDA BLA	2015-05-05	2017-05-05
Commercial IND Master files	2015-05-05	2018-05-05

C. Types of Submissions That Are Exempted From the Electronic Submission Requirement Described in This Guidance Document

Section 745A(a) allows FDA to establish exemptions from the electronic submission requirements. Accordingly, FDA has exempted all submissions regarding noncommercial INDs from the requirements under section 745A(a).[9] For purposes of this guidance, the term *noncommercial products* refers to products that are not intended to be distributed commercially and includes investigator-sponsored INDs and expanded access INDs (e.g., emergency use INDs and treatment INDs).

Although these submissions will be exempt, FDA also accepts their submission electronically as described in this guidance document.

We hope to release the revised form in October.