

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

Purpose: FDA is requesting a non-substantive change to Form FDA 1571 currently approved under OMB Control No. 0910-0014.

We are requesting the addition of the following two fields:

Field 7B: SNOMED CT

SNOMED CT (Systematized Nomenclature of Medicine -- Clinical Terms) is a standardized, multilingual vocabulary of clinical terminology that is used by physicians and other health care providers for the electronic exchange of clinical health information. SNOMED CT currently contains more than 300,000 medical concepts, divided into hierarchies as diverse as body structure, clinical findings, geographic location and pharmaceutical/biological product. Each concept is represented by an individual number and several concepts can be used simultaneously to describe a complex condition.

7B. SNOMED CT Indication Disease Term (Use continuation page for each additional indication and respective coded disease term)
--

Field 12: Combination Product

21st Century Cures Legislation requires that Sponsors identify combination products.

12. For Originals, is the product a combination product (21 CFR 3.2(e))? <input type="checkbox"/> Yes <input type="checkbox"/> No	Combination Product Type (See instructions)	Request for Designation (RFD) Number
---	---	--------------------------------------

Justification: SNOMED CT provides a standard by which medical conditions and symptoms can be referred, eliminating the confusion that may result from the use of regional or colloquial terms.

The inclusion of Combination Products on the form helps meet the 21st Century Cures Legislation requirement.

We hope to release the revised form in early May 2018.