

Logical Observation Identifiers Names and Codes (LOINC) for Human Prescription Drug and Biological Product Labeling

(For questions about this document please contact the [Labeling Policy Team](#) in the Office of New Drugs in the Center for Drug Evaluation and Research at the Food and Drug Administration.)

For human prescription drug and biological products, this document links [LOINC names and codes](#) to:

- (1) Sections and subsections of Physician Labeling Rule (PLR) and “old” format Prescribing Information (PI) (see Tables 1 and 2);
- (2) Types of FDA-approved patient labeling [Patient Information (known as Patient Package Inserts (PPI), Medication Guide (MG), and Instructions for Use (IFU))] (see Table 3); and
- (3) The principal display panel on carton and/or container labeling (see Table 4)

When creating Structured Product Labeling (SPL), FDA encourages applicants to select the most specific, appropriate LOINC name/code to allow SPL users to identify content within each section and subsection of the PI and to identify content in the other types of prescription drug labeling (e.g., PPI, MG, IFU, or carton/container labeling). Use the LOINC name “SPL UNCLASSIFIED SECTION” (and associated code) only when no appropriate LOINC name/code is available for the specific section/subsection of the PI (see Tables 1 and 2). Some specific considerations are described below.

- For FDA-approved MG, PPI, and IFU, select only from one of the three LOINC names/codes listed in Table 3. Avoid use of the LOINC names/codes listed in Tables 1, 2, and 4, and avoid use of the LOINC name “SPL UNCLASSIFIED SECTION” (and associated code). For example:
 - If there is an FDA-approved MG, use the LOINC name “SPL MEDGUIDE SECTION” and associated LOINC code “42231-1”.
- The LOINC names “RENAL IMPAIRMENT SUBSECTION” and “HEPATIC IMPAIRMENT SUBSECTION” (and associated codes) are reserved for the USE IN SPECIFIC POPULATIONS section in PLR labeling (see Table 1). Therefore, avoid use of these LOINC names (and associated codes) for subsections in other sections of the PI. For example, if there is a subsection title in the DOSAGE AND ADMINISTRATION section about dosing in patients with:
 - Renal impairment (e.g., subsection title is “Recommended Dosage in Patients with Renal Impairment”), use the LOINC name “SPL UNCLASSIFIED SECTION” (and associated code) for that subsection, rather than the LOINC name “RENAL IMPAIRMENT SUBSECTION” (and associated code).
 - Hepatic impairment (e.g., subsection title is “Recommended Dosage in Patients with Hepatic Impairment”), use the LOINC name “SPL UNCLASSIFIED SECTION” (and associated code) for that subsection, rather than the LOINC name “HEPATIC IMPAIRMENT SUBSECTION” (and associated code).

**Table 1: HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS
PLR FORMAT PRESCRIBING INFORMATION***

Full Prescribing Information

LOINC Code	LOINC Name	Section/Subsection Name as Per 21 CFR 201.56(d) and 201.57(c) or by Guidance
34066-1	BOXED WARNING SECTION	BOXED WARNING section
34067-9	INDICATIONS & USAGE SECTION	1 INDICATIONS AND USAGE section
34068-7	DOSAGE & ADMINISTRATION SECTION	2 DOSAGE AND ADMINISTRATION section
43678-2	DOSAGE FORMS & STRENGTHS SECTION	3 DOSAGE FORMS AND STRENGTHS section
34070-3	CONTRAINDICATIONS SECTION	4 CONTRAINDICATIONS section
43685-7	WARNINGS AND PRECAUTIONS SECTION	5 WARNINGS AND PRECAUTIONS section
34084-4	ADVERSE REACTIONS SECTION	6 ADVERSE REACTIONS section
90374-0	CLINICAL TRIALS EXPERIENCE SECTION	6.1 Clinical Trials Experience subsection
90375-7	POSTMARKETING EXPERIENCE SECTION	6.2 Postmarketing Experience subsection
34073-7	DRUG INTERACTIONS SECTION	7 DRUG INTERACTIONS section
43684-0	USE IN SPECIFIC POPULATIONS SECTION	8 USE IN SPECIFIC POPULATIONS section
42228-7	PREGNANCY SECTION	8.1 Pregnancy subsection
77290-5	LACTATION SECTION	8.2 Lactation subsection <i>[[for PLLR format]]</i>
34079-4	LABOR & DELIVERY SECTION	8.2 Labor and Delivery subsection <i>[[for non-PLLR format]]</i>
77291-3	FEMALES & MALES OF REPRODUCTIVE POTENTIAL SECTION	8.3 Females and Males of Reproductive Potential subsection <i>[[for PLLR format]]</i>
34080-2	NURSING MOTHERS SECTION	8.3 Nursing Mothers subsection <i>[[for non-PLLR format]]</i>
34081-0	PEDIATRIC USE SECTION	8.4 Pediatric Use subsection
34082-8	GERIATRIC USE SECTION	8.5 Geriatric Use subsection
88828-9	RENAL IMPAIRMENT SUBSECTION	Renal Impairment subsection
88829-7	HEPATIC IMPAIRMENT SUBSECTION	Hepatic Impairment subsection
42227-9	DRUG ABUSE AND DEPENDENCE SECTION	9 DRUG ABUSE AND DEPENDENCE section
34085-1	CONTROLLED SUBSTANCE SECTION	9.1 Controlled Substance subsection
34086-9	ABUSE SECTION	9.2 Abuse subsection
34087-7	DEPENDENCE SECTION	9.3 Dependence subsection
34088-5	OVERDOSAGE SECTION	10 OVERDOSAGE section
34089-3	DESCRIPTION SECTION	11 DESCRIPTION section
34090-1	CLINICAL PHARMACOLOGY SECTION	12 CLINICAL PHARMACOLOGY section
43679-0	MECHANISM OF ACTION SECTION	12.1 Mechanism of Action subsection
43681-6	PHARMACODYNAMICS SECTION	12.2 Pharmacodynamics subsection
43682-4	PHARMACOKINETICS SECTION	12.3 Pharmacokinetics subsection
49489-8	MICROBIOLOGY SECTION	12.4 Microbiology subsection
66106-6	PHARMACOGENOMICS SECTION	12.5 Pharmacogenomics subsection
88830-5	IMMUNOGENICITY	12.6 Immunogenicity subsection
43680-8	NONCLINICAL TOXICOLOGY SECTION	13 NONCLINICAL TOXICOLOGY section
34083-6	CARCINOGENESIS & MUTAGENESIS & IMPAIRMENT OF FERTILITY SECTION	13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility subsection
34091-9	ANIMAL PHARMACOLOGY & OR TOXICOLOGY SECTION	13.2 Animal Toxicology and/or Pharmacology subsection
34092-7	CLINICAL STUDIES SECTION	14 CLINICAL STUDIES section
34093-5	REFERENCES SECTION	15 REFERENCES section
34069-5	HOW SUPPLIED SECTION	16 HOW SUPPLIED/STORAGE AND HANDLING section
88436-1	PATIENT COUNSELING INFORMATION	17 PATIENT COUNSELING INFORMATION section

* Omit clearly inapplicable sections or subsections

**Table 2: HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS
“OLD” FORMAT PRESCRIBING INFORMATION[&]**

LOINC Code	LOINC Name	Section/Subsection Name as Per 21 CFR 201.56(e) and 201.80
34066-1	BOXED WARNING SECTION	BOXED WARNING section
34089-3	DESCRIPTION SECTION	DESCRIPTION section
34090-1	CLINICAL PHARMACOLOGY SECTION	CLINICAL PHARMACOLOGY section
34067-9	INDICATIONS & USAGE SECTION	INDICATIONS AND USAGE section
34070-3	CONTRAINDICATIONS SECTION	CONTRAINDICATIONS section
34071-1	WARNINGS SECTION	WARNINGS section
42232-9	PRECAUTIONS SECTION	PRECAUTIONS section
34072-9	GENERAL PRECAUTIONS SECTION	General subsection
34076-0	INFORMATION FOR PATIENTS SECTION	Information for Patients subsection
34075-2	LABORATORY TESTS SECTION	Laboratory Tests subsection
34073-7	DRUG INTERACTIONS SECTION	Drug Interactions subsection
34074-5	DRUG & OR LABORATORY TEST INTERACTIONS SECTION	Drug/Laboratory Test Interactions subsection
34083-6	CARCINOGENESIS & MUTAGENESIS & IMPAIRMENT OF FERTILITY SECTION	Carcinogenesis, Mutagenesis, Impairment of Fertility subsection
42228-7	PREGNANCY SECTION	Pregnancy subsection
34079-4	LABOR & DELIVERY SECTION	Labor and Delivery subsection
34080-2	NURSING MOTHERS SECTION	Nursing Mothers subsection
34081-0	PEDIATRIC USE SECTION	Pediatric Use subsection
34082-8	GERIATRIC USE SECTION	Geriatric Use subsection
34084-4	ADVERSE REACTIONS SECTION	ADVERSE REACTIONS section
42227-9	DRUG ABUSE AND DEPENDENCE SECTION	DRUG ABUSE AND DEPENDENCE section
34088-5	OVERDOSAGE SECTION	OVERDOSAGE section
34068-7	DOSAGE & ADMINISTRATION SECTION	DOSAGE AND ADMINISTRATION section
34069-5	HOW SUPPLIED SECTION	HOW SUPPLIED section
34091-9	ANIMAL PHARMACOLOGY & OR TOXICOLOGY SECTION	ANIMAL PHARMACOLOGY AND/OR ANIMAL TOXICOLOGY section
34092-7	CLINICAL STUDIES SECTION	CLINICAL STUDIES section
34093-5	REFERENCES SECTION	REFERENCES section

[&] Omit clearly inapplicable sections or subsections

**Table 3: HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS
FDA-APPROVED PATIENT LABELING**

LOINC Code	LOINC Name	Type of FDA-Approved Patient Labeling [^]
59845-8	INSTRUCTIONS FOR USE SECTION	Instructions for Use (IFU)
42231-1	SPL MEDGUIDE SECTION	Medication Guide (MG)
42230-3	SPL PATIENT PACKAGE INSERT SECTION	Patient Information (also called Patient Package Insert (PPI))

[^] Prescription drug labeling may include an IFU and/or either a MG or PPI; but does not include a MG and a PPI.

**Table 4: HUMAN PRESCRIPTION DRUG AND BIOLOGICAL PRODUCTS CARTON
AND/OR CONTAINER LABELING**

LOINC Code	LOINC Name	Part of Carton/Container Labeling
51945-4	PACKAGE LABEL. PRINCIPAL DISPLAY PANEL	Principal Display Panel (part of a container label or carton labeling)