Follow-On Biologics Workshop

Intro to Naming Discussion:

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Federal Trade Commission

Should Adverse Event Reports Rely on Drug Name Only?

ENOXAPARIN SODIUM

INJECTABLE;INTRAVENOUS, SUBCUTANEOUS; 300mg/3mL (100mg/mL) – Vials

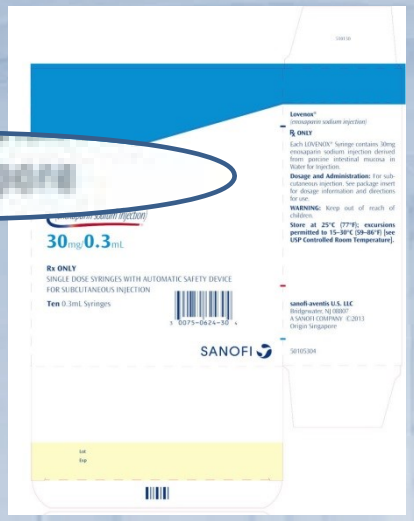
Drug Name	Active Ingredients	TE Code	Company	Labeler	NDC Codes
ENOXAPARIN SODIUM	ENOXAPARIN SODIUM	AB	SANDOZ INC	SANDOZ	0781-3122-93
LOVENOX	ENOXAPARIN SODIUM	AB	SANOFI AVENTIS US	SANOFI	0075-0626-04 0075-0626-03 0075-8030-01
LOVENOX	ENOXAPARIN SODIUM	AB	SANOFI AVENTIS US	WINTHROP (AUTHORIZED GEN.)	0955-1016-01

INJECTABLE;SUBCUTANEOUS; 30mg/0.3mL (100mg/mL) - Pre-Filled Syringes

Drug Name	Active Ingredients	TE Code	FDA Applicant	Labeler	NDC Codes
LOVENOX (PRESERVATIVE FREE)	ENOXAPARIN SODIUM	AP	SANOFI AVENTIS US	SANOFI-AVENTIS U.S. LLC	0075-0624-31 0075-0624-30 0075-8013-10
LOVENOX (PRESERVATIVE FREE)	ENOXAPARIN SODIUM	AP	SANOFI AVENTIS US	CARDINAL HEALTH	55154-4024-5 55154-4037-5
ENOXAPARIN SODIUM (PRESERVATIVE FREE)	ENOXAPARIN SODIUM	AP	SANOFI AVENTIS US	WINTHROP (AUTHORIZED GEN.)	0955-1003-10
ENOXAPARIN SODIUM (PRESERVATIVE FREE)	ENOXAPARIN SODIUM	AP	AMPHASTAR PHARM	WATSON PHARMA, INC.	62037-839-20
ENOXAPARIN SODIUM (PRESERVATIVE FREE)	ENOXAPARIN SODIUM	AP	SANDOZ	SANDOZ	0781-3119-63

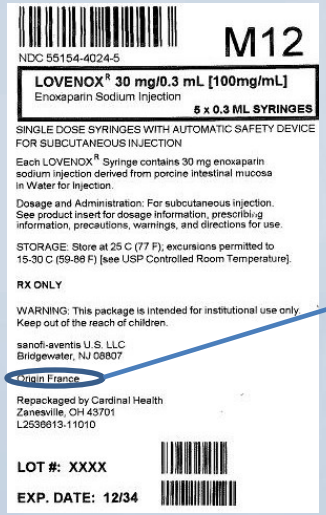
Even for Branded Drugs, Are The Names Sufficient?

NDC 0075-0624-31

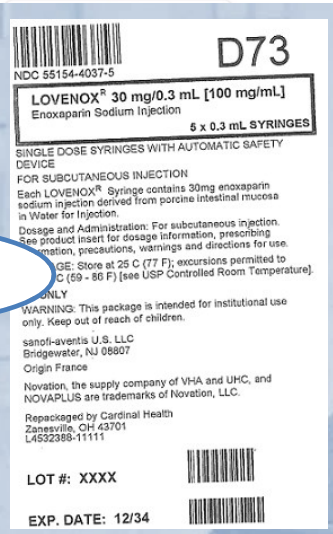


NDC 0075-0624-30

NDC 0075-8013-10



NDC 55154-4024-5

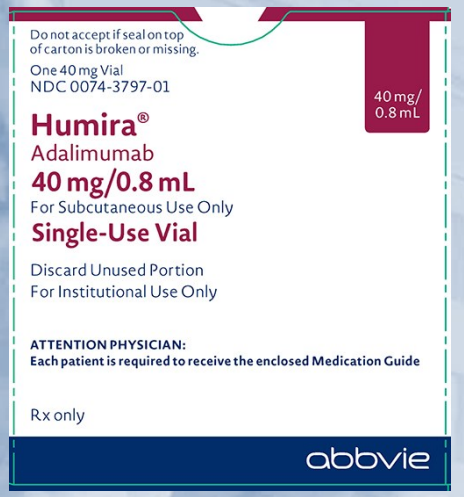


NDC 55154-4037-5

Is The Name Sufficient for Identifying a Biologic With Many Different NDC Codes?

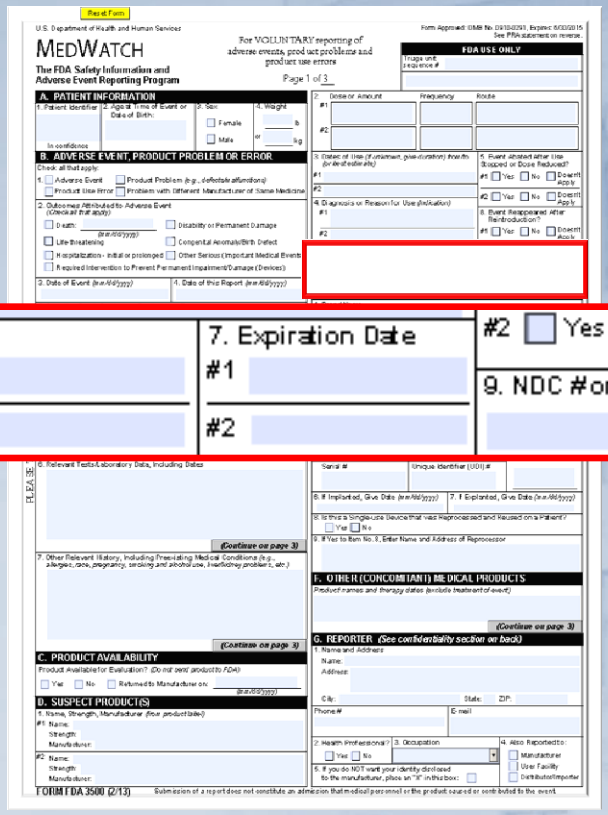
Pre-Filled Syringes (Pediatric and Adult Doses)

Pre-Filled Pens (including Crohn's Disease and Psoriasis Packages)

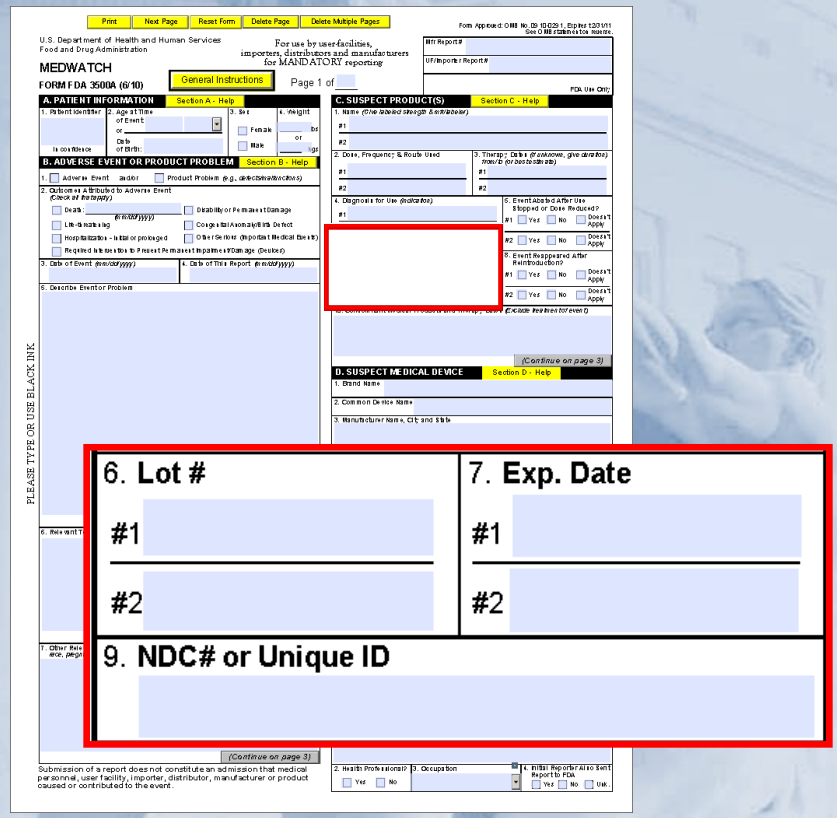


Vials

Adverse Event Reports Can Capture NDC Codes



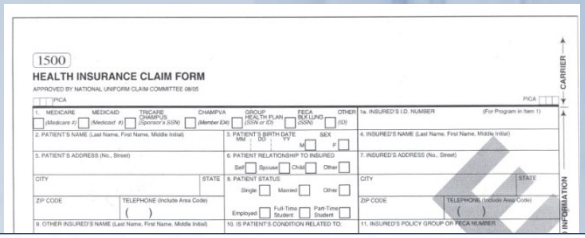
FDA 3500 - Voluntary Reporting For Medical Professionals



FDA 3500A - Mandatory Reporting For User-Facilities, Importers, Distributors, and Manufacturers

Will Doctors Report NDC Codes?

- NDC Codes Have Been Required To Obtain Medicaid Rebates And Are Used on Common Forms, such as CMS-1500:


1500

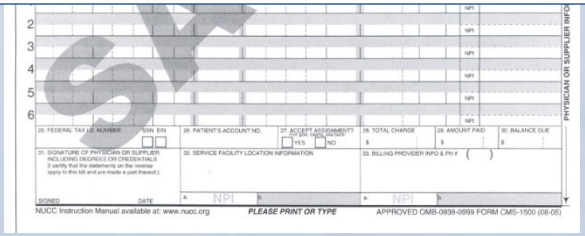
HEALTH INSURANCE CLAIM FORM

APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 08/05

PICA

CARRIER

INFORMATION


PHYSICIAN OR SUPPLIER INFO

NUCC Instruction Manual available at: www.nucc.org

PLEASE PRINT OR TYPE

APPROVED OMB-0938-0999 FORM CMS-1500 (08-05)

NDC Code:

24. A. DATE(S) OF SERVICE From MM	DD	YY	To MM	DD	YY	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCPCS	MODIFIER	E. DIAGNOSIS POINTER	F. $ CHARGES	G. DAYS OR UNITS	H. EPSDT Family Plan	I. ID. QUAL.	J. RENDERING PROVIDER ID. #
N4			Immune Globulin Intravenous						UN2				N	1B	12345678901
10	01	05	10	01	05	11		J1563		13	500 00	20	N	NPI	0123456789

(Source: CMS Manual System, Pub 100-04 Medicare Claims Processing) (Dec. 21, 2007)