February 16, 2021

VIA ELECTRONIC MAIL

Lonnie Smith
Office of Health Informatics, Office of Chief Scientist,
Office of Commissioner, Food and Drug Administration,
10903 New Hampshire Ave.
Building 32. Office 2231
Silver Spring, MD 20993-0002
Email: *lonnie.smith@fda.hhs.gov*

RE: Follow up request to add new Marketing Category for Drug Products Produced by Federally Registered Outsourcing Facilities (OSF) pursuant to Section 503B of the Federal Food, Drug and Cosmetic Act that engage in the compounding of human drug products

Dear Mr. Smith:

In regard to the email response received on April 22, 2020, NCPDP would like to clarify the request to create a new Structured Product Labeling (SPL) marketing category of "Outsourcing Facility Compounded Drug Product" for those drug products compounded by OSF.

NCPDP agrees with your statement that the SPL document type "Human Compounded Drug Label" has been utilized to identify drug products which are produced by OSF. This categorization is appropriate for drugs compounded by these facilities. Furthermore, NCPDP agrees the current FDA title for business operation for the establishment registration as a "human drug compounding outsourcing facilities" is appropriate.

However, NCPDP believes the SPL marketing category of "Unapproved Drug Other" inconsistently describes drug products produced by OSF and leads to confusion and other challenges; specifically:

1. Drugs produced in an OSF are exempt from the approval process. Such compounded drug products are lawfully produced and subject to inspection, quality and labeling requirements that are the basis for the exemption. The more appropriate term to use for these products is "exempt from approval" per FDA 503B regulations; the terminology used should be accurate and consistent, including the marketing category.
2. The marketing category database is where third-party payers, Pharmacy Benefits Managers (PBMs) and other payers first identify a product within the electronic claim adjudication process. The actual SPL document type database is rarely, if ever, utilized and the category of "Unapproved Drug Other" leads to rejected or delayed approval of claims.
3. A hospital, physician or patient may mistakenly assume a compound drug product from an OSF is unlawful, because it is marketed as "unapproved drug other,".

The addition of a new marketing category specific to drug products produced by OSF will unify the terminology to be consistent with current guidance documents and minimize confusion to consumers and payers. NCPDP notes there are already marketing categories for nutritional supplements, medical foods, medical devices and others (Exhibit A). FDA has also set precedent with other unique and specific

categories for *actual* unapproved drugs that can be legally sold, for example "homeopathic" and "medical gas." Inclusion of a distinct marketing category for drug products compounded by OSF aligns with the established FDA model for marketing categories.

For the reasons outlined herein, NCPDP respectfully requests FDA create a new marketing category within SPL titled "Outsourcing facility compound drug product" for drug products produced by Registered Outsourcing Falicities.

Respectfully,

Lee Ann C. Stember
President & CEO
National Council for Prescription Drug Programs (NCPDP)
9240 E. Raintree Drive
Scottsdale, AZ 85260
(480) 477-1000 x 108
lstember@ncpdp.org

For direct inquiries or questions related to this letter, please contact:

Paul Wilson
Technical Analyst, Standards Development
NCPDP
standards@ncpdp.org

cc:
NCPDP Board of Trustees

Enclosure

Exhibit A

Source: National Cancer Institute Thesaurus

NCI concept code for Marketing Category: C73581

NCI Thesaurus OID: 2.16.840.1.113883.3.26.1.1

SPL Acceptable Term	Code
ANADA	C73583
ANDA	C73584
Approved Drug Product Manufactured Under Contract	C132333
BLA	C73585
Bulk ingredient	C73626
Bulk Ingredient For Animal Drug Compounding	C98252
Bulk Ingredient For Human Prescription Compounding	C96793
Conditional NADA	C73588
Cosmetic	C86965
Dietary Supplement	C86952
Drug for Further Processing	C94795
Exempt device	C80438
Export only	C73590
Humanitarian Device Exemption	C80440
IND	C75302
Medical Food	C86964
Legally Marketed Unapproved New Animal Drugs for Minor Species	C92556
NADA	C73593
NDA	C73594
NDA authorized generic	C73605
OTC Monograph Drug Product Manufactured Under Contract	C132334
OTC monograph final	C73603
OTC monograph not final	C73604
*Outsourcing Facility Compounded Drug Product	C73599 Suggested
Premarket Application	C80441
Premarket Notification	C80442
SIP Approved Drug	C175463
Unapproved drug for use in drug shortage	C101533
Unapproved Drug Other	C73627 Current
Unapproved Drug Product Manufactured Under Contract	C132335
Unapproved homeopathic	C73614
Unapproved medical gas	C73613

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