

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

20-725

PROPRIETARY NAME REVIEW(S)

CONSULTATION RESPONSE
Division Of Medication Errors And Technical Support
Office Of Drug Safety
(DMETS; HFD-420)

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TO:
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HFD-180

THROUGH:
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HFD-180

PRODUCT NAME:

CREON® 5
CREON® 10
CREON® 20

MINIMICROSPHERES®

(Pancrealipase Delayed-Release Capsules, USP)
5, 000 USP Units, 10,000 USP Units, and 20,000 USP Units

NDA #: 20-725

NDA SPONSOR:

Solvay Pharmaceuticals

SAFETY EVALUATOR: Linda Y. Kim-Jung, R.Ph.

SUMMARY: In response to a consult from the Division of Gastro-Intestinal and Coagulation Drug Products (HFD-180), the Division of Medication Errors and Technical Support (DMETS) conducted a review of the proposed proprietary name "Creon Minimicrospheres" to determine the potential for confusion with approved proprietary and established names as well as pending names.

RECOMMENDATIONS:

1. DMETS does not recommend the use of the modifier "Minimicrospheres" in conjunction with the proprietary name, Creon.
2. In order to avert potential errors associated with the Creon product lines, DMETS recommends the sponsor revise the proprietary name so that the numerical modifiers, "5", "10", and "20" reads "5,000", "10,000", and "20,000". The latter clearly represents the lipase components are not numbers that would likely be misinterpreted as the number of capsules per dose.
3. DMETS recommends implementation of the labeling revisions described in Section III of this review to minimize potential errors with the use of this product.
4. DMETS also recommends that the manufacturers disseminate appropriate education materials, such as a Dear Pharmacist Letter, to inform healthcare professionals of the changes with numerical modifiers pertaining to Creon.
5. DDMAC objects to the name "Creon Minimicrospheres" because DDMAC objects to the fanciful description of the dosage form, unless the product is described as "minimicrospheres" in the final package insert.

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PROPRIETARY NAME REVIEW

DATE OF REVIEW: July 30, 2003
NDA NUMBER: 20-725
NAME OF DRUG: CREON MINIMICROSPHERES
(Pancrealipase Delayed-Released Capsules, USP)
NDA SPONSOR: Solvay Pharmaceuticals

I. INTRODUCTION

This consult was written in response to a request from the Division of Gastro-Intestinal and Coagulation Drug Products (HFD-180) for assessment of the tradename "Creon Minimicrospheres", regarding potential name confusion with other proprietary or established drug names. This product is one of the many pancreatic enzyme drug products already marketed without an approved NDA. The sponsor introduced CREON Microspheres products to the U.S. market in 1987 (CREON 5, 10, 20). In 1993, the microsphere product was replaced with the Minimicrospheres product. The current product is available in three strengths: 5,000, 10,000, and 20,000 USP Units of lipase. The sponsor has now submitted and NDA for the Minimicrospheres products.

PRODUCT INFORMATION

Creon Minimicrospheres Capsules are orally administered and contain delayed-release Minimicrospheres of porcine-derived pancreatic lipase. Creon Minimicrospheres Capsules are indicated for adult and pediatric patients with exocrine pancreatic insufficiency as is often associated with, but not limited to cystic fibrosis, chronic pancreatitis, postpancreatectomy, postgastrointestinal bypass surgery, ductal obstruction of the pancreas or common bile duct. Creon Minimicrospheres Capsules are a pancreatic enzyme product prescribed to improve digestion of food, especially fat. Clinical experience dictates initial starting dose. The usual dose is based on the lipase component and is as follows. Pancreatic Enzyme Dosing in Cystic Fibrosis: weight based enzyme dosing should begin with 1,000 USP lipase units/kg/meal for children less than four years of age and with 500 USP lipase units/kg/meal for those over age four. Dosage should be adjusted according to the severity of the disease, control of steatorrhea and maintenance of good nutritional status. Pancreatic enzyme dosing in other exocrine pancreatic insufficiency disorders should be individualized and determined by the degree of maldigestion and malabsorption, the fat content of the diet and lipase activity of each preparation. The usual initial starting dosage is 10,000-20,000 lipase units per meal or snack. The number of capsules or capsule strength given with meals or snacks should be estimated by assessing which dose minimizes steatorrhea and maintains good nutritional status. Creon is available as capsules with the following enzyme potencies.

	Creon 5 Minimicrospheres	Creon 10 Minimicrospheres	Creon 20 Minimicrospheres
Lipase, USP units	5,000	10,000	20,000
Protease, USP units	18,750	37,500	75,000
Amylase, USP units	16,600	33,200	66,400

II. RISK ASSESSMENT

The DMETS medication error staff conducted a search of several standard published drug product reference texts¹ as well as several FDA databases² for existing drug names which sound-alike or look-alike to “Creon” to a degree where potential confusion between drug names could occur under the usual clinical practice settings. The Saegis³ Pharma-In-Use database was searched for drug names with potential for confusion. An Expert Panel discussion was conducted to review all findings from the searches. In addition, DMETS conducted three prescription analysis studies, to simulate the prescription ordering process.

A. EXPERT PANEL DISCUSSION

An Expert Panel discussion was held by DMETS to gather professional opinions on the safety of the proprietary name, Creon Minimicrospheres. Potential concerns regarding drug marketing and promotion related to the proposed name were also discussed. This group is composed of DMETS Medication Errors Prevention Staff and representation from the Division of Drug Marketing, Advertising, and Communications (DDMAC). The group relies on their clinical and other professional experiences and a number of standard references when making a decision on the acceptability of a proprietary name.

1. The Expert Panel identified the proprietary name, “Aceon” and “Creon” (the existing Creon product on market) as having the potential for confusion with Creon Minimicrospheres. In addition, the panel was also concerned that the first portion of the proprietary name, “Creon” may look like Cream. These products are listed in Table 1 (see page 4) along with the dosage forms available and usual dosage. The proposed proprietary name, Creon Minimicrospheres is the same product as the existing product in the market and upon NDA approval, Creon Minimicrospheres will replace the existing Creon product lines in the market place. The existing and the proposed product are both Minimicrospheres formulation, and thus “Creon” will not be discussed in this review.
2. DDMAC objects to the name “Creon Minimicrospheres” because “Minimicrospheres” is a fanciful description of the dosage form, unless the product is described as a “minimicrospheres” in the final package insert.

¹ Facts and Comparisons, 2003, Facts and Comparisons, St. Louis, MO. <http://www.efactsweb.com/index.asp> MICROMEDEX Integrated Index, 2003, MICROMEDEX, Inc., 6200 South Syracuse Way, Suite 300, Englewood, Colorado 80111-4740, which includes all products/databases within ChemKnowledge, DrugKnowledge, and RegsKnowledge Systems and PDR/Physician’s Desk Reference (Medical Economics Company Inc, 2003).

² The Division of Medication Errors and Technical Support [DMETS] database of Proprietary name consultation requests, New Drug Approvals 98-03, and the electronic online version of the FDA Orange Book.

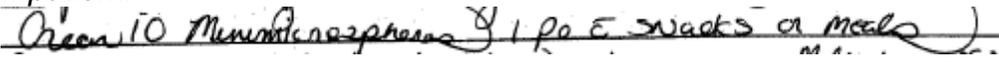
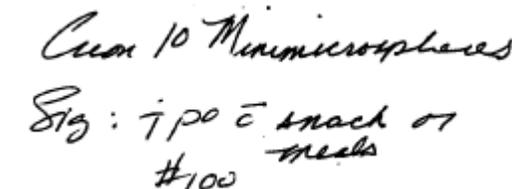
³ Data provided by Thomson & Thomson’s SAEGIS™ Online Service, available at www.thomson-thomson.com

Table 1 Potential Sound-Alike/Look-Alike Names Identified by DMETS Expert Panel			
Product Name	Dosage form(s), Established name	Usual adult dose*	Other**
CREON® 5 CREON® 10 CREON® 20 MINIMICROSPHERES® (Pancrelipase Delayed-Release Capsules, USP) 5,000 USP Units, 10,000 USP Units, and 20,000 USP Units	Delayed-Release Capsules (Pancrelipase Delayed-Release Capsules, USP)	Pancreatic Enzyme Dosing in Cystic Fibrosis: weight based enzyme dosing should begin with 1,000 USP lipase units/kg/meal for children less than four years of age and with 500 USP lipase units/kg/meal for those over age four. Dosage should be adjusted according to the severity of the disease, control of steatorrhea and maintenance of good nutritional status. Pancreatic Enzyme Dosing in Other Exocrine Pancreatic Insufficiency Disorders: dosage should be individualized and determined by the degree of maldigestion and malabsorption, the fat content of the diet and lipase activity of each preparation. The usual initial starting dosage is 10,000-20,000 lipase units per meal or snack. The number of capsules or capsule strength given with meals or snacks should be estimated by assessing which dose minimizes steatorrhea and maintains good nutritional status.	N/A
“CREON” The current CREON on the market is also minimicrospheres.	Delayed-Release Capsules (Pancrelipase Delayed-Release Capsules, USP)	Pancreatic Enzyme Dosing in Cystic Fibrosis: weight based enzyme dosing should begin with 1,000 USP lipase units/kg/meal for children less than four years of age and with 500 USP lipase units/kg/meal for those over age four. Dosage should be adjusted according to the severity of the disease, control of steatorrhea and maintenance of good nutritional status. Pancreatic Enzyme Dosing in Other Exocrine Pancreatic Insufficiency Disorders: dosage should be individualized and determined by the degree of maldigestion and malabsorption, the fat content of the diet and lipase activity of each preparation. The usual initial starting dosage is 10,000-20,000 lipase units per meal or snack. The number of capsules or capsule strength given with meals or snacks should be estimated by assessing which dose minimizes steatorrhea and maintains good nutritional status.	LA/SA
ACEON	Tablets (Perindopril Erbumine) 2 mg, 4 mg, and 8 mg tablets	The recommended initial dose is 4 mg once daily. The usual maintenance dose range is 4 to 8 mg administered as a single dose. It also may be administered in 2 divided doses. The dosage may be titrated upward until blood pressure, when measured just before the next dose, is controlled or to a maximum of 16 mg/day.	LA
The word, “Cream.”	N/A	N/A	LA

B. PRESCRIPTION ANALYSIS STUDIES

1. Methodology for **Creon Minimicrospheres** capsules studies

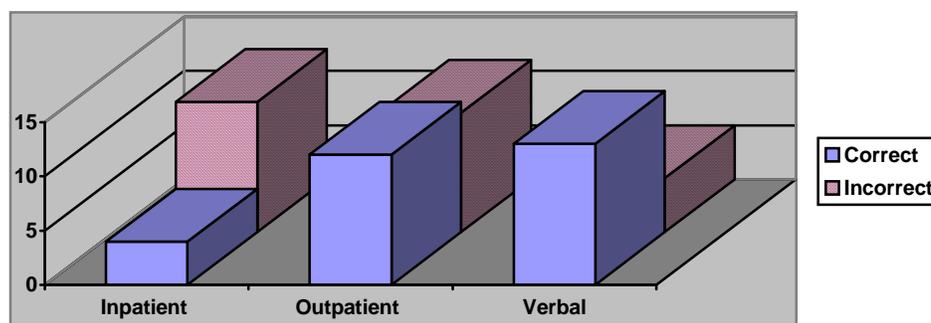
Studies were conducted within FDA for the proposed proprietary name to determine the degree of confusion of Creon Minimicrospheres with other U.S. drug names due to similarity in visual appearance with handwritten prescriptions or verbal pronunciation of the drug name. These studies employed a total of 127 health care professionals (nurses, pharmacists, and physicians). This exercise was conducted in an attempt to simulate the prescription ordering process. DMETS staff members wrote inpatient and outpatient prescriptions for Creon Minimicrospheres, each consisting of a combination of marketed and unapproved drug products. These written prescriptions were optically scanned and one prescription was delivered via e-mail to each study participant. In addition, one DMETS staff member recorded a verbal outpatient prescription that was then delivered to a group of study participants via telephone voicemail. Each reviewer was then requested to provide an interpretation of the prescription via e-mail.

HANDWRITTEN PRESCRIPTIONS	VERBAL PRESCRIPTION
CREON	
<i>Inpatient:</i> 	
<i>Outpatient:</i> 	<i>Verbal:</i> "...Creon 10 Minimicrospheres, take one by mouth with meals and snack."

2. Results for Creon Minimicrospheres capsules studies

Results of these exercises are summarized below:

Study	No. of participants	# of responses (%)	Correctly Interpreted (%)	Incorrectly Interpreted (%)
Written: Inpatient	43	16 (37%)	4 (25%)	12 (75%)
Written Outpatient	41	23 (56%)	12 (52%)	11 (48%)
Verbal:	43	18 (42%)	13 (72%)	5 (28%)
Total:	127	57 (45%)	29 (51%)	28 (49%)



When examining the interpretations from the written inpatient prescriptions, 4 of 16 (25%) respondents interpreted the name correctly. In addition, 12 of the 23 respondents (52%) from the written outpatient prescriptions interpreted the name correctly. The misinterpretation from the inpatient study included *Creon 10 minimicrospheres, Crean-10 minimicrospheres, Creon, Creon 10, Creon 10 Microspheres, Green 10 minimicrospheres, Orear 10 mucophosphere, Oreca 10 Minimicrospheres, Oreca 10 Minimicrospheres, Orecin Minimicrospheres, Oreen 10 minimicrospheres, and Oven 10 Minimic02phases*. One respondent who interpreted the writing sample as *Crean-10 minimicrospheres* also noted that the writing sample could also look like *Cream*. The misinterpretations from the written outpatient study

included Cuon 10 Minimicrospheres, Creon 10, Creon 10 microspheres, cuan 10 minimicrocapusles, cum 10 Minimicrospheres, Cuon 10 minimicrosphases, Curox 10 minimicrospheres, cusa 10 minimicrospheres, Cuse minimicrospheres. None of the misinterpretations represent names of currently marketed drug products.

In the verbal study of 5 of 18 (28 %) respondents interpreted Creon 10 Minimicrosphees incorrectly. The misinterpretations were phonetic variations of Creon 10 Minimicropsheres. These included Cilon-10 minimicrospheres, Creanon 10 mini micro spheres, Creaon 10 minimicrospheres, Creon 10, and Creon 10 microspheres. None of the misinterpretations represent names of currently marketed drug products.

C. ADVERSE EVENT REPORTING SYSTEM (AERS) and DRUG QUALITY REPORTING SYSTEM (DQRS) DATABASE SEARCHES

DMETS searched the FDA Adverse Event Reporting System (AERS) database on August 4, 2003 in order to determine any post-marketing safety reports of medication errors associated with Creon products. The MedDRA Preferred Terms (PT), "Medication Error", "Accidental Overdose", "Overdose NOS", and "Pharmaceutical Product Complaint" and the drug names, "Creon%" and "pancrelipase%" were used to perform the search. This search did not retrieve any reports involving Creon products, but the search retrieved one medication error report of another pancrelipase-containing product, Viokase 8. A brief synopsis of this report is listed below. The Drug Quality Reporting System (DQRS) database was also searched on August 4, 2003 for medication error reports with the search terms, "Creon%" and "pancrealipas%". The DQRS search did not retrieve any medication error reports involving pancrealipase products.

ISR# 3863166-8

A physician ordered "Viokase 8 tabs with meals TID" for a hospitalized patient. A pharmacist intervened to prevent the patient from taking 8 tablets of Viokase. The correct order was as follows: "Viokase 8 three tablets with meals TID."

D. SAFETY EVALUATOR RISK ASSESSMENT

1. Look-alike potential with Aceon

The root name of the proposed name, Creon Minimicrospheres looks similar to Aceon and could cause potential name confusion for the following reasons. Aceon and the first portion of the proposed name, Creon Minimicrospheres may look-alike (see page 8) when scripted. Aceon (Perindopril Erbumine) is an angiotensin-converting enzyme inhibitor used for the treatment of patients with essential hypertension. It may also be used alone or given with other classes of antihypertensives, especially thiazide diuretics. The recommended initial dose is 4 mg once daily. The usual maintenance dose range is 4 to 8 mg administered as a single dose. It also may be administered in 2 divided doses. The dosage may be titrated upward until blood pressure, when measured just before the next dose, is controlled or to a maximum of 16 mg/day. Aceon is available as 2 mg, 4 mg, and 8 mg tablets. Both products share the letter "C" in the first syllable and ends with the letters, "EON". These similarities contribute to the look-alike characteristics of Creon and Aceon. Although both products are oral drugs, different characteristics such as the dosage forms, strengths, and

dosing intervals will help distinguish between the two products. Both products, Creon and Aceon are available in multiple strengths [Creon 5 (5,000 units), 10 (10,000 units), and 20 (20,000 units) capsules and Aceon 2 mg, 4 mg, and 8 mg tablets.] Thus, strength will likely be indicated on a prescription for either of these products and additionally, there are no overlapping strengths. Despite the strong look-alike characteristics of Aceon and Creon, differences such as the strength, dosing schedules (TID for Creon vs. QD or BID for Aceon), and different patient population will help minimize the potential for name confusion between these two products.

Creon Aceon

2. Numerical Modifiers in the Proprietary Name

The proprietary name, Creon Minimicrospheres is expressed with the numerical modifiers (Creon 5 Minimicrospheres, Creon 10 Minimicrospheres, or Creon 20 Minimicrospheres). Other pancrelipase products often have similar nomenclature. For example, Viokase is expressed with the numerical modifiers (8 or 16). DMETS is concerned with the potential for errors associated with products containing numerical modifiers in the proprietary name. DMETS has received a medication error report involving Viokase 8 where the numerical modifier “8” was confused as “the number of tablets” needed per dose rather than as an expression of the number of lipase units. The numerical modifier represents the lipase component of Creon (i.e., “5” represents 5,000 USP Units of lipase, “10” represents 10,000 USP Units of lipase, and “20” represent 20,000 USP Units of lipase). We acknowledge the need to differentiate the three strengths, however, we discourage the use of numerical modifiers that can be misinterpreted as “the number of capsules” to be taken or to be dispensed. At this time, the Agency has not received any medication error reports involving Creon products. However, aforementioned Viokase medication error indicates the potential for confusion when a number modifier is used. DMETS is concerned that a similar type of medication error could occur with Creon, because the proprietary name also utilizes numerical modifiers (5, 10, 20) that could be misinterpreted as the number of tablets needed per dose. If a patient ingests a high dose of Creon, a patient could experience toxicity. Overdoses of pancreatic enzyme concentrate may cause diarrhea or transient intestinal upset. Extremely high doses of exogenous pancreatic enzymes have been associated with hyperuricemia and hyperuricosuria.

Therefore, DMETS discourages the use of numerical modifiers as a part of the proprietary name, because the numerical modifiers 5, 10, 20 could be misinterpreted as the number of doses to be dispensed and may lead to confusion resulting in medication errors and/or patient harm. To avert potential errors with the Creon product line, DMETS recommends that Solvay revise the names Creon 5, Creon 10, and Creon 20 to Creon 5,000, Creon 10,000, and Creon 20,000. This is similar to what DMETS requested of the manufacturer of Viokase.

3. Dosage Form Modifiers in Proprietary Name

The sponsored introduced CREON Microspheres product in the U.S. market in 1987 (Creon 5, 10, and 20). In 1993, the microsphere product was replaced with the minimicrosphere product. The current product is available in three strengths: 5,000,

10,000, and 20,000 USP Units of lipase. Currently, the proposed proprietary name is a combination the tradename, CREON®, strength (5, 10, 20), and dosage form, MINIMICROSPHERES® (e.g., CREON® 10 MINIMICROSPHERES®). Since, Creon is available in only one formulation (Minimicrospheres), DMETS questions the necessity of stating the dosage form as part of the proprietary name. The minimicrosphere (dosage form) technology can be stated in the established name or be described in the package insert to prevent crowding of the labeling and to increase the prominence of the established name (Pancrelipase Delayed-release Capsules, USP) and strength (See Figure 1). See Figure 2 for an example of a product labeling for Retin-A-Micro, which states their “microsphere” technology in the established name.



Figure 1. Current labeling of Creon products.



Figure 2. Product labeling for Retin-A Micro.

III. COMMENTS TO SPONSOR

DMETS does not recommend the use of the proprietary name, Creon Minimicrospheres for the following reasons.

1. Numerical Modifiers in the Proprietary Name

The proprietary name, Creon Minimicrospheres is expressed with the numerical modifiers (Creon 5 Minimicrospheres, Creon 10 Minimicrospheres, or Creon 20 Minimicrospheres). Other pancrelipase products often have similar nomenclature. For example, Viokase is expressed with the numerical modifiers (8 or 16). DMETS is concerned with the potential for errors associated with products containing numerical modifiers in the proprietary name. DMETS has received a medication error report involving Viokase 8 where the numerical modifier “8” was confused as “the number of tablets” needed per dose rather than as an expression of the number of lipase units. The numerical modifier represents the lipase component of Creon (i.e., “5” represents 5,000 USP Units of lipase, “10” represents 10,000 USP Units of lipase, and “20” represent 20,000 USP Units of lipase). We acknowledge the need to differentiate the three strengths, however, we discourage the use of numerical modifiers that can be misinterpreted as “the number of capsules” to be taken or to be dispensed. At this time, the Agency has not received any medication error reports involving Creon products. However, aforementioned Viokase medication error indicates the potential for confusion when a number modifier is used. DMETS is concerned that a similar type of medication error could occur with Creon, because the proprietary name also utilizes numerical modifiers (5, 10, 20) that could be misinterpreted as the number of tablets needed per dose. If a patient ingests a high dose of Creon, a patient could experience toxicity. Overdoses of pancreatic enzyme concentrate may cause diarrhea or transient intestinal upset. Extremely high doses of exogenous pancreatic enzymes have been associated with hyperuricemia and hyperuricosuria.

Therefore, DMETS discourages the use of numerical modifiers as a part of the proprietary name, because the numerical modifiers 5, 10, 20 could be misinterpreted as the number of doses to be dispensed and may lead to confusion resulting in medication errors and/or patient harm. To avert potential errors with the Creon product line, DMETS recommends that Solvay revise the names Creon 5, Creon 10, and Creon 20 to Creon 5,000, Creon 10,000, and Creon 20,000.

2. Dosage Form Modifiers in Proprietary Name

The sponsored introduced CREON Microspheres product in the U.S. market in 1987 (Creon 5, 10, and 20). In 1993, the microsphere product was replaced with the minimicrosphere product. The current product is available in three strengths: 5,000, 10,000, and 20,000 USP Units of lipase. Currently, the proposed proprietary name is a combination the tradename, CREON®, strength (5, 10, 20), and dosage form, MINIMICROSPHERES® (e.g., CREON® 10 MINIMICROSPHERES®). Since, Creon is available in only one formulation (Minimicrospheres), DMETS questions the necessity of stating the dosage form as part of the proprietary name. The minimicrosphere (dosage form) technology can be stated in the established name or be described in the package insert to prevent crowding of the labeling and to increase the prominence of the established name (Pancrelipase Delayed-release Capsules, USP) and strength (See Figure 1). See

Figure 2 for an example of a product labeling for Retin-A-Micro, which states their “microsphere” technology in the established name.



Figure 1. Current labeling for Creon products.



Figure 2. Product labeling for Retin-A Micro.

3. Additionally, DMETS reviewed the container labels and carton and insert labeling of CREON MINIMICROSPHERES, in attempts to focus on the safety issues relating to possible medication errors. DMETS has identified the following areas of possible improvement, in an effort to minimize potential user error.

A. GENERAL COMMENTS

1. The presentation of the labels and labeling for Creon Minimicrospheres were provided in black and white, and may not represent the true color of the labels and labeling. Therefore, DMETS cannot assess if there are any safety concerns due to the colors utilized on the labels and labeling. Additionally, DMETS was unable to conduct a complete review of the labeling due to the illegibility of the container labels. Ensure that there is color differentiation for the different strengths of Creon Minimicrospheres.
2. Currently, the proposed proprietary name is a combination the tradename, CREON®, strength (5, 10, 20), and dosage form, MINIMICROSPHERES® (e.g., CREON® 5 MINIMICROSPHERES®). Since, Creon is available in only one formulation (Minimicrospheres), DMETS questions the necessity of stating the dosage form as part of the proprietary name. The minimicrosphere

(dosage form) technology can be described in the package insert, rather than stating the dosage form as part of the proprietary name on the label and labeling, as this can crowd the labeling and decrease the prominence of the established name (Pancrelipase Delayed-release Capsules, USP). Delete the modifier, Minimicrospheres, on the principal display. The Minimicrospheres technology can be defined in the product package insert.

B. INSERT LABELING

1. DOSAGE AND ADMINISTRATION

- a. Line 109 states  (b) (4)

- b. Add the following information to Information for Patients:
 - i. Lines 109, **CONTRAINDICATIONS**  (b) (4)

(
b
)
(
4
)
 - ii. Line 113-114, **WARNINGS**:  (b) (4)

 - iii. Line 275-279, **DOSAGE AND ADMINISTRATION**:  (b) (4)

- c. Line 221 and 240: Define rows “At risk”, “Without any AE”, and “Any Adverse Event” in Table 1.
- d. Line 240: Define rows “At risk”, “Without any AE”, and “Any Adverse Event” in Table 2.
- e. Line 267 to 268: When stating “Doses should be taken during meals or snacks...” specify number of meals per day (i.e., 3 times a day with breakfast, lunch, and dinner) as the number of meals per day is subjective and could vary individually.

- f. Line 267: Change the sentence, “Do not take without food” to be more direct and assertive (e.g., Must be taken with food).
- g. Line 277: Provide examples of soft food with a pH less than 5.5.

IV. RECOMMENDATIONS

- A. DMETS does not recommend the modifier “MINIMICROSPHERES” in conjunction with the proprietary name, Creon.
- B. In order to avert potential errors associated with the Creon product lines, DMETS recommends the sponsor revise the proprietary name so that the numerical modifiers “5”, “10”, and “20” read “5,000”, “10,000”, and “20,000”. The latter clearly represents the lipase components are not numbers that would likely be misinterpreted as the number of tablets per dose.
- C. DMETS recommends implementation of the labeling revisions outlined in section III of this review to minimize potential errors with the use of this product
- D. DMETS also recommends that the manufacturers disseminate appropriate education materials, such as a Dear Pharmacist Letter, to inform healthcare professionals of the changes with numerical modifiers pertaining to Creon.
- E. DDMAC objects to the name, “Creon Minimicrospheres”. DDMAC objects to the fanciful description of the dosage form, unless the product is described as a “minimicrospheres” in the final package insert.

DMETS would appreciate feedback of the final outcome of this consult (e.g., copy of revised labels/labeling). We are willing to meet with the Division for further discussion as well. If you have any questions concerning this review, please contact Sammie Beam at 301-827-3242.

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Safety Evaluator
Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety

Concur:

Denise Toyer, Pharm.D. Date
Team Leader
Division of Medication Errors and Technical Support (DMETS)
Office of Drug Safety

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/s/

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