Amendment #77-273 ANDA

Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Capsules (Equivalent to 10 mg Hydrocodone Bitartrate and 8 mg Chlorpheniramine Maleate) & (Equivalent to 5 mg Hydrocodone Bitartrate and 4 mg Chlorpheniramine Maleate)

October 22, 2004

tyco Healthcare

Mallinckrodt

Mallinckrodt Inc.
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Tele: 314 654-2000
www.mallinckrodt.com

PATENT AMENDMENT

October 22, 2004

Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Attention: Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, Maryland 20855-2773

RE: ANDA# 77-273 Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Capsules (Equivalent to 10 mg Hydrocodone Bitartrate and 8 mg Chlorpheniramine Maleate) & (Equivalent to 5 mg Hydrocodone Bitartrate and 4 mg Chlorpheniramine Maleate)

Dear Madame or Sir:

Mallinckrodt has concurrently submitted this Patent Amendment to ANDA #77-273 for Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Capsules (Equivalent to 10 mg Hydrocodone Bitartrate and 8 mg Chlorpheniramine Maleate) & (Equivalent to 5 mg Hydrocodone Bitartrate and 4 mg Chlorpheniramine Maleate) which was originally submitted to the Agency on September 9, 2004. Included in this amendment is a letter which certifies that notice containing the information required under 21 CFR 314.95(c) was sent to the patent owner and holder of the approved application.

This original amendment consists of one (1) volume. An archival copy is being filed in a blue folder and a technical review copy is being filed in a red folder. In addition, a field copy is being sent to the district office in Buffalo, New York. This field copy is contained in a maroon folder.

Correspondence related to this submission should be addressed to Melissa D. Cay, Mallinckrodt Inc., 675 McDonnell Blvd., PO Box 5840, St. Louis, Missouri 63134. For additional information, please contact me at 314-654-3514 or call Ronald T. Groman, Manager, Regulatory Affairs at 314-654-6060.

Sincerely,

Melissa D. Cay
Sr. Regulatory Affairs Associate
Phone: 314-654-3514
FAX: 314-654-6496

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675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Tele: 314 654-2000
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PATENT AMENDMENT- FIELD COPY

October 22, 2004

District Director, Buffalo, New York District Office
Food and Drug Administration
Olympic Towers, Suite 100
300 Pearl Street
Buffalo, New York 14202

RE: ANDA# 77-273 Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Capsules (Equivalent to 10 mg Hydrocodone Bitartrate and 8 mg Chlorpheniramine Maleate) & (Equivalent to 5 mg Hydrocodone Bitartrate and 4 mg Chlorpheniramine Maleate)

Dear Madam or Sir:

Mallinckrodt has concurrently submitted this Patent Amendment to ANDA #77-273 for Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Capsules (Equivalent to 10 mg Hydrocodone Bitartrate and 8 mg Chlorpheniramine Maleate) & (Equivalent to 5 mg Hydrocodone Bitartrate and 4 mg Chlorpheniramine Maleate) which was originally submitted to the Agency on September 9, 2004. Included in this amendment is a letter which certifies that notice containing the information required under 21 CFR 314.95(c) was sent to the patent owner and holder of the approved application.

This original application, which has been submitted to CDER in Rockville, Maryland, is also being provided to your office and the District Office in Buffalo, NY. This field copy is contained in (1) maroon folder.

Correspondence related to this submission should be addressed to Melissa D. Cay, Mallinckrodt Inc., 675 McDonnell Blvd., PO Box 5840, St. Louis, Missouri 63134. For additional information, please contact me at 314-654-3514 or call Ronald T. Groman, Manager, Regulatory Affairs at 314-654-6060.

Sincerely,

Melissa D. Cay
Sr. Regulatory Affairs Associate
Fax: 314-654-6496

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION TO MARKET A NEW DRUG, BIOLOGIC, OR AN ANTIBIOTIC DRUG FOR HUMAN USE

(Title 21, Code of Federal Regulations, Parts 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: August 31, 2005
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
Tyco Healthcare Mallinckrodt	10/22/04
TELEPHONE NO. (*Include Area Code*)	**FACSIMILE** (*FAX*) **Number** (*Include Area Code*)
(314) 654-3514	(314) 654-6496
APPLICANT ADDRESS (*Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued*):	**AUTHORIZED U.S. AGENT NAME & ADDRESS** (*Number, Street, City, State, Country, ZIP Code, telephone & FAX number*) IF APPLICABLE
675 McDonnell Blvd. PO Box 5840 St. Louis, MO 63134	

PRODUCT DESCRIPTION

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (*If previously issued*) 77-273

ESTABLISHED NAME (*e.g., Proper name, USP/USAN name*)	PROPRIETARY NAME (*trade name*) IF ANY
Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Capsules	TussiCaps™

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME (*If any*)
sulfonated styrene-divinylbenzene copolymer complex with 4,5a-epoxy-3-methoxy-17-methylmorphinan-6-one. sulfonated styrene-divinylbenzene copolymer complex with 2-[p-chloro-a-[2-(dimethylamino)ethyl]-benzyl]pyridine.

CODE NAME (*If any*)

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Capsules	equivalent to 10 mg Hydrocodone Bitartrate and 8 mg Chlorpheniramine & equivalent to 5 mg Hydrocodone Bitartrate and 4 mg Chlorpheniramine Maleate	oral

(PROPOSED) INIDCATION(S) FOR USE:
relief of cough and upper respiratory symptoms associated with allergy or a cold

APPLICATION DESCRIPTION

APPLICATION TYPE (*check one*) ☐ NEW DRUG APPLICATION (CDA, 21 CFR 314.50) ☒ ABBREVIATED NEW DRUG APPLICATION (ANDA, 21 CFR 314.94) ☐ BIOLOGICS LICENSE APPLICATION (BLA, 21 CFR Part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b)(1) ☐ 505 (b)(2)

IF AN ANDA, OR 505(b)(2), IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug: Tussionex Pennkinetic (hydrocodone polistirex and chlorpheniramine polistirex) Extended-Release Suspension

Holder of Approved Application: Celltech Pharmaceuticals, Inc.

TYPE OF SUBMISSION (*check one*) ☐ ORIGINAL APPLICATION ☒ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION ☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

IF A SUBMISSION OR PARTIAL APPLICATION, PROVIDE LETTER DATE OF AGREEMENT TO PARTIAL SUBMISSION:

IF A SUPPLEMENT, IDENTIFY THE APPROPRIATE CATEGORY ☐ CBE ☐ CBE-30 ☐ Prior Approval (PA)

REASON FOR SUBMISSION
Patent Amendment

PROPOSED MARKETING STATUS (*check one*) ☐ PRESCRIPTION PRODUCT (Rx) ☐ OVER THE COUNTER PRODUCT (OTC)

NUMBER OF VOLUMES SUBMITTED 1 THIS APPLICATION ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION (Full establishment information should be provided I the body of the Application.)
Provide locations of all manufacturing, packaging and control sites for drug substance and drug product (continuation sheets may be used if necessary). Include name, address, contact, telephone number, registration number (CFN), DMF number, and manufacturing steps and/or type of testing (e.g. Final dosage form, Stability testing) conducted at this site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

See original application

Cross References (list related License Applications, INDs, NDAs, PMAs, 510(k)s, IDEs, BMFs, and DMFs referenced in the current application)

See original application

This application contains the following items: *(Check all that apply)*		
☐	1.	Index
☐	2.	Labeling *(check one)* ☐ Draft Labeling ☐ Final Printed Labeling
☐	3.	Summary (21 CFR 314.50 (c))
☐	4.	Chemistry section
☐		A. Chemistry, manufacturing, and controls information (e.g., 21 CFR 314.50(d)(1); 21 CFR 601.2)
☐		B. Samples (21 CFR 314.50 (e)(1); 21 CFR 601.2 (a)) (Submit only upon FDA's request)
☐		C. Methods validation package (e.g., 21 CFR 314.50(e)(2)(i); 21 CFR 601.2)
☐	5.	Nonclinical pharmacology and toxicology section (e.g., 21 CFR 314.50(d)(3); 21 CFR 601.2)
☐	6.	Human pharmacokinetics and bioavailability section (e.g., 21 CFR 314.50(d)(3)
☐	7.	Clinical Microbiology (e.g., 21 CFR 31.50(d)(4)
☐	8.	Clinical data section (e.g., 21 CFR 314.50(d)(5); 21 CFR 601.2)
☐	9.	Safety update report (e.g., 21 CFR 314.50(d)(5)(vi)(b); 21 CFR 601.2)
☐	10.	Statistical section (e.g., 21 CFR 314.50(d)(6); 21 CFR 601.2)
☐	11.	Case report tabulations (e.g., 21 CFR 314.50(f)(1); 21 CFR 601.2)
☐	12.	Case report forms (e.g., 21 CFR 314.50(f)(2); 21 CFR 601.2)
☐	13.	Patent information on any patent which claims the drug (21 U.S.C. 355 (b) or (c))
☐	14.	A patent certification with respect to any patent which claims the drug (21 U.S.C. 355 (b)(2) or (j)(2)(A))
☐	15.	Establishment description (21 CFR Part 600, if applicable)
☐	16.	Debarment certification (FD&C Act 306 (k)(1))
☒	17.	Field copy certification (21 CFR 314.50(l)(3))
☐	18.	User Fee Cover Sheet (Form FDA 3397)
☐	19.	Financial Information (21 CFR Part 54)
☒	20.	OTHER *(Specify)* Patent Amendment

CERTIFICATION

I agree to update this application with new safety information about the product that may reasonably affect the statement of contraindications, warnings, precautions, or adverse reactions in the draft labeling. I agree to submit safety update reports as provided for by regulation or as requested by FDA. If this application is approved, I agree to comply with all applicable laws and regulations that apply to approved applications, including, but not limited to the following:

1. Good manufacturing practice regulations in 21 CFR Parts 210, 211 or applicable regulations, Parts 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR Parts 201, 606, 610, 660, and/or 809.
4. In the case of a prescription drug or biological product, prescription drug advertising regulations in 21 CFR Part 202.
5. Regulations on making changes in application in FD&C Act section 506A, 21 CFR 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on Reports inn 21 CFR 314.80, 314.81, 600.80, and 600.81.
7. Local, state and Federal environmental impact laws.

If this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, I agree not to market the product until the Drug Enforcement Administration makes a final scheduling decision.

The data and information I this submission have been reviewed and, to the best of my knowledge are certified to be true and accurate.

Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
	Melissa D. Cay, Sr. Regulatory Affairs Associate	10/22/04
ADDRESS *(Street, City, State, and Zip Code)*		Telephone Number
675 McDonnell Blvd. PO Box 5840, St. Louis, MO 63134		(314) 654-3514

Public reporting burden for this collection of information is estimated to average 24 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to:

Department of Health and Human Services
Food and Drug Administration
CDER, HFD-99
1401 Rockville Pike
Rockville, MD 20852-1448

Food and Drug Administration
CDER (HFD-94)
12229 Wilkins Avenue
Rockville, MD 20852

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it display a currently valid OMB control number.

tyco
Healthcare
Mallinckrodt

Jeffrey S. Boone, J.D.
Assistant General Counsel
direct: 1 (314) 654-8955
fax: 1 (314) 654-3156

Mallinckrodt Inc.
675 McDonnell Boulevard
PO Box 5840
St. Louis, MO 63134

2004 October 22

CERTIFICATION REGARDING TRANSMISSION OF PARAGRAPH IV NOTICE

Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended Release Capsules

10 mg / 8 mg
(equivalent to 10 mg hydrocodone bitartrate and 8 mg chlorpheniramine maleate)

and

5 mg / 4 mg
(equivalent to 5 mg hydrocodone bitartrate and 4 mg chlorpheniramine maleate)

ANDA 77-273

The applicant makes the following certification in connection with its Abbreviated New Drug Application identified above.

Transmittal of Paragraph iv Notice [21 CFR 314.95(b)]
The applicant, Mallinckrodt Inc., certifies that notice of applicant's paragraph iv certification has been sent by certified mail, with return receipt requested to:

(1) each owner of the patent or the representative designated by the owner to receive the notice:

Celltech Manufacturing, Inc.
Legal Affairs Office
755 Jefferson Road
Rochester, NY 14623-1710

and

(2) the holder of the approved application under section 505(b) of the Act for the listed drug claimed by the patent and for which the applicant is seeking approval:

Celltech Pharmaceuticals, Inc.
Legal Affairs Office
755 Jefferson Road
Rochester, NY 14623-1710

The Applicant further certifies that each notice met the content requirements under 21 CFR 314.95(c).

Mallinckrodt Inc.

by: Jeffrey S. Boone

Jeffrey S. Boone, J.D.
Assistant General Counsel

Q:\JSB\Job Files - Named\Hydrocodone Px + Chlor Px P-iv notice cert.doc

tyco
Healthcare

Mallinckrodt

Mallinckrodt Inc.
675 McDonnell Boulevard
P.O. Box 5840
St. Louis, MO 63134

Tele: 314 654-2000
www.mallinckrodt.com

FIELD COPY CERTIFICATION

Mallinckrodt Inc. hereby certifies that pursuant to 21 C.F.R. §314.94(d)(5) a field copy of this PATENET AMENDMENT for ANDA #77-273 for Hydrocodone Polistirex and Chlorpheniramine Polistirex Extended-Release Capsules (Equivalent to 10 mg Hydrocodone Bitartrate and 8 mg Chlorpheniramine Maleate) & (Equivalent to 5 mg Hydrocodone Bitartrate and 4 mg Chlorpheniramine Maleate) has been prepared and submitted to the District Office in Buffalo, NY concurrently with the archival and review copies. This field copy contains a true and accurate copy of the information prepared to satisfy requirements of technical Section 21 C.F.R. §314.94(a)(9) contained in the archival and review copies of this original ANDA.

Melissa D. Cay
Responsible Agent

10/22/04
Date

Con