CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER

20-911

Correspondence

St. Paul, MN 55144-1000

September 14, 2000

Robert Meyer, MD
Director, Division of Pulmonary and Allergy Drug Products (HFD-570)
Center for Drug Evaluation and Research
Food and Drug Administration
Room 10B-45
5600 Fishers Lane
Rockville, MD 20857

Subject: **Amendment 035 to NDA 20-911**
QVAR™ (beclomethasone dipropionate HFA) Inhalation Aerosol
Final Draft Labeling for Package Insert and Agreement to Minor Revision in the Text of the Carton

Attn: **Ms. Sandra Barnes**

Dear Dr. Meyer:

In accordance with 21 CFR 314.60, 3M Pharmaceuticals submits in duplicate Amendment 35 to NDA 20-911. Per our telephone conversation earlier today, accompanying this letter is the final draft package insert for QVAR. In addition, 3M Pharmaceuticals commits to increase the prominence of the words "Inhalation Aerosol" found in the proprietary name on the product carton to match the size, font and prominence of the text in the established name. This will be done prior to printing initial packaging materials for distribution.

Also, in this amendment you will find a revised Commercial Stability Commitment. 3M commits to, submitting a supplement for prior approval under 21 CFR 314.70 to obtain an extension of the expiry period for any product configuration. Such a supplement will be supported by standard 3-lot regression analysis as described by the FDA draft guidance "Stability Testing of Drug Substance and Drug Products" (June, 1998), demonstrating that the product has a calculated shelf-life of at least the proposed expiry date.

Thank you for incorporating this amendment into NDA 20-911, and for the opportunity to continue to dialogue as we progress toward approval of this NDA. Please contact me (651 736-5015) if there are any questions or concerns regarding this amendment.

Respectfully,

D. M. Markoe, Jr.

David M. Markoe, Jr.
Senior Regulatory Specialist
3M Pharmaceuticals

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, 314 & 601)

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on page 2.

FOR FDA USE ONLY

APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
3M Pharmaceuticals	September 14, 2000
TELEPHONE NO. *(Include Area Code)* (651) 736-5015	**FACSIMILE (FAX) Number** *(Include Area Code)* (651) 737-0485
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued):* 3M Center, Bldg 270-3A-08 St. Paul, MN 55144-1000	**AUTHORIZED U.S. AGENT NAME & ADDRESS** *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION QVAR™

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (If previously issued) NDA 20-911

ESTABLISHED NAME *(e.g., Proper name, USP/USAN name)*	PROPRIETARY NAME *(trade name)* IF ANY
Beclomethasone Dipropionate USP	QVAR ™

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(If any)*

CODE NAME *(If any)*

DOSAGE FORM:	STRENGTHS:	ROUTE OF ADMINISTRATION:
Inhalation Aerosol	80 mcg and 40 mcg	oral inhalation

(PROPOSED) INDICATION(S) FOR USE: QVAR™ is indicated for maintenance treatment of asthma as prophylactic therapy, and is also indicated for asthma patients who require systemic corticosteroid treatment where administration of Qvar may reduce or eliminate the need for systemic corticosteroids

APPLICATION INFORMATION

APPLICATION TYPE (check one)

☒ NEW DRUG APPLICATION (21 CFR 314.50) ☐ ABBREVIATED APPLICATION (ANDA, AADA, 21 CFR 314.94)

☐ BIOLOGICS LICENSE APPLICATION (21 CFR part 601)

IF AN NDA, IDENTIFY THE APPROPRIATE TYPE ☐ 505 (b) (1) ☒ 505 (b) (2) ☐ 507

IF AN ANDA, OR AADA, IDENTIFY THE REFERENCE LISTED DRUG PRODUCT THAT IS THE BASIS FOR THE SUBMISSION

Name of Drug — Holder of Approved Application

TYPE OF SUBMISSION (check one)

☐ ORIGINAL APPLICATION ☒ AMENDMENT TO A PENDING APPLICATION ☐ RESUBMISSION

☐ PRESUBMISSION ☐ ANNUAL REPORT ☐ ESTABLISHMENT DESCRIPTION SUPPLEMENT ☐ SUPAC SUPPLEMENT

☐ EFFICACY SUPPLEMENT ☐ LABELING SUPPLEMENT ☐ CHEMISTRY MANUFACTURING AND CONTROLS SUPPLEMENT ☐ OTHER

REASON FOR SUBMISSION Request approval to market a new drug

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

NUMBER OF VOLUMES SUBMITTED 1

THIS APPLICATION IS ☒ PAPER ☐ PAPER AND ELECTRONIC ☐ ELECTRONIC

ESTABLISHMENT INFORMATION

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 the site. Please indicate whether the site is ready for inspection or, if not, when it will be ready.

Amendment to a pending application, Not Applicable

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

IND — DMF — DMF — DMF — DMF — DMF — DMF —

This application contains the following items: (Check all that apply)	
	1. Index
X	2. Labeling (check one) ☒ Draft Labeling ☐ Final Printed Labeling
	3. Summary (21 CFR 314.50(c))
	4. Chemistry section
X	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) (2), 21 CFR 601.2)
	6. Human pharmacokinetics and bioavailability section (e.g. 21 CFR 314.50 (d) (3), 21 CFR 601.2)
	7. Clinical Microbiology (e.g. 21 CFR 314.50 (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 (k) (3))
	18. User Fee Cover Sheet (Form FDA 3397)
	19. OTHER (Specify)

CERTIFICATION

I agree to update this application with new safety information about the drug 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 210 and 211, 606, and/or 820.
2. Biological establishment standards in 21 CFR Part 600.
3. Labeling regulations in 21 CFR 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 202.
5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.99, and 601.12.
6. Regulations on reports in 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 in 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
D.M. Markoe Jr.	David M. Markoe, Jr. Senior Regulatory Specialist	9/14/00

ADDRESS (Street, City, State, Zip Code)	Telephone Number
3M Center, Bldg 260-6A-22;St. Paul, MN 55144-1000	(651) 736-5015

Public reporting burden for this collection of information is estimated to average 40 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:

DHHS, Reports Clearance Officer
Paperwork Reduction Project (0910-0338)
Hubert H. Humphrey Building, Room 531-H
200 Independence Avenue, S.W.
Washington, DC 20201

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Please DO NOT RETURN this form to this address.

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pages of trade secret and/or confidential commercial information

3M Pharmaceuticals
3M Center Building 260-6A-22
St.Paul, MN 55144-1000

August 6, 1998

3M

John Jenkins, MD, Director
Division of Pulmonary Drug Products (HFD-570)
Center for Drug Evaluation and Research
Food and Drug Administration
Document Control Room 10B-03
5600 Fishers Lane
Rockville, MD 20857

Subject: **Amendment 001 to NDA 20-911**
QVAR™, Beclomethasone Dipropionate in Propellant HFA 134a
Notification to Glaxo Wellcome Inc. Non-Infringement of
U.S. Patent No. 4,364,923

Dear Dr. Jenkins:

In accordance with Section 505(b)(3) of the Food, Drug, and Cosmetic Act, 3M Pharmaceuticals has provided notice to Glaxo Wellcome and ——— that 3M has filed NDA 20-911. A copy of the letter mailed to each firm is attached and indicates that 3M has certified to the FDA that claims of patent no. 4,363,932 will not be infringed by the manufacture, use, or sale of a Beclomethasone Dipropionate metered aerosol inhalation drug product by 3M.

Certified mail receipts are also attached and indicate that both Glaxo Wellcome and ——— 's received the letter on July 28, 1998. In accordance with Section 505(c)3(C) of the FDC Act, Glaxo Wellcome and ——— have 45 days to bring forth patent infringement action. This 45 day period expires on September 11, 1998.

If you have any questions or concerns regarding this notification please contact me at (651) 733-3543.

Sincerely,

Mark A. Morken

Mark A. Morken
Advanced Regulatory Associate

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Form Approved: OMB No. 0910-0338
Expiration Date: April 30, 2000
See OMB Statement on page 2.

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

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

FOR FDA USE ONLY
APPLICATION NUMBER

APPLICANT INFORMATION

NAME OF APPLICANT	DATE OF SUBMISSION
3M Pharmaceuticals	August 6, 1998
TELEPHONE NO. *(Include Area Code)* (651) 733-3543	FACSIMILE (FAX) Number *(Include Area Code)* 651-737-4065
APPLICANT ADDRESS *(Number, Street, City, State, Country, ZIP Code or Mail Code, and U.S. License number if previously issued)*: 3M Center, Bldg 260-6A-22 St. Paul, MN 55144-1000	AUTHORIZED U.S. AGENT NAME & ADDRESS *(Number, Street, City, State, ZIP Code, telephone & FAX number)* IF APPLICABLE

PRODUCT DESCRIPTION QVAR™

NEW DRUG OR ANTIBIOTIC APPLICATION NUMBER, OR BIOLOGICS LICENSE APPLICATION NUMBER (if previously issued) NDA20-911

ESTABLISHED NAME (e.g., *Proper name, USP/USAN name*)	PROPRIETARY NAME *(trade name)* IF ANY
Beclomethasone Dipropionate, USP	Qvar™

CHEMICAL/BIOCHEMICAL/BLOOD PRODUCT NAME *(if any)* | CODE NAME *(if any)*

DOSAGE FORM: Inhalation Aerosol | STRENGTHS: 80 mcg and 40mcg | ROUTE OF ADMINISTRATION: oral inhalation

(PROPOSED) INDICATION(S) FOR USE: QVAR is indicated for maintenance treatment of asthma as prophylactic therapy, and is also indicated for asthma patients who require system corticosteroid treatment, where administration of QVAR may reduce or eliminate the need for systemic corticosteroids

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5. Regulations on making changes in application in 21 CFR 314.70, 314.71, 314.72, 314.97, 314.98, and 601.12.
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SIGNATURE OF RESPONSIBLE OFFICIAL OR AGENT	TYPED NAME AND TITLE	DATE
D.M. Markoe, Jr.	Dave M. Markoe, Jr. Regulatory Specialist	Aug 6, 1998

ADDRESS (Street, City, State, Zip Code)	Telephone Number
3M Center, Bldg 260-4A-22, St. Paul, MN 55144-1000	(651) 736-8015

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Food and Drug Administration
Rockville MD 20857

NDA 20-911

3M Pharmaceuticals
Bldg. 260-6A-22
3M Center
St. Paul, MN 55144-1000

JUL 17 1998

Attention: David M. Markoe, Jr.
Regulatory Specialist

Dear Mr. Markoe:

We have received your new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Qvar (beclomethasone dipropionate in HFA-134a) Inhalation Aerosol

Therapeutic Classification: Standard (S)

Date of Application: May 11, 1998

Date of Receipt: May 12, 1998

Our Reference Number: 20-911

Unless we notify you within 60 days of our receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on July 12, 1998 in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be May 12, 1998.

Please cite the NDA number listed above at the top of the first page of any communications concerning this application.

If you have any questions, contact Sandy Barnes, Project Manager, at (301) 827-1050.

Sincerely,

/S/

Cathie Schumaker, R.Ph.
Chief, Project Management Staff
Division of Pulmonary Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

cc:
Archival NDA 20-911
HFD-570/Div. Files
HFD-570/S.Barnes
DISTRICT OFFICE

Drafted by: SBarnes/June 8, 1998
Initialed by:
final:
filename: 20911.WPD

ACKNOWLEDGEMENT (AC)

/S/
7/17/98.

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