

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number NDA 21-108

CHEMISTRY REVIEW(S)

U.S. FOOD and DRUG ADMINISTRATION

OFFICE OF NEW DRUG CHEMISTRY

DIVISION OF DERMATOLOGIC AND DENTAL DRUG PRODUCTS
—Review of Chemistry, Manufacturing, and Controls—

NDA #: 21-108

CHEM.REVIEW #: 1

REVIEW DATE: June 2, 2000

JUN 5 2000

<u>SUBMISSION/TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
ORIGINAL	31-AUG-99	03-SEP-99	04-SEP-99
BZ	25-OCT-99	26-OCT-99	26-OCT-99
BZ	16-DEC-99	17-DEC-99	17-DEC-99

NAME & ADDRESS OF APPLICANT:Johnson & Johnson Consumer Companies
199 Grandview Road
Skillman, NJ 08558

Contact:

Paul Manley
Worldwide Director
Regulatory Affairs
(908) 874-1239DRUG PRODUCT NAMEProprietary:Nonproprietary/USAN:Alternate Names:Code Names/ #'s:Chemical Type:Therapeutic Class:

Renova

Tretinoin

retinoic acid or all-*trans*-retinoic acid

RWJ 8203

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PATENT STATUS:Renova (tretinoin emollient cream) 0.02% is covered by
the following patents:

U.S. Patent No. 4,423,041(1983)

U.S. Patent No. 4,603,146(1986)

U.S. Patent No. 4,877,805(1989)

These patents are in effect.

PHARMACOLOGICAL INDICATION:Adjunctive agent for mitigation of fine wrinkles,
hyperpigmentation, and tactile roughness of facial skin.DOSAGE FORM:STRENGTHS:ROUTE OF ADMINISTRATION:DISPENSED:

cream

0.02%

topical

X R. OTC

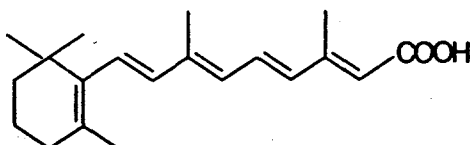
CHEMICAL NAME, STRUCTURAL FORMULA, MOLC. FORMULA & WT:

(all-E)-3,7-dimethyl-9-(2,6,6-trimethyl-1-cyclohexen-1-yl)-2,4,6,8-nonatetraenoic acid

Common name: retinoic acid, tretinoin

CAS number: 302-79-4

Structure:



SUPPORTING DOCUMENTS:

IND	_____	Note: This IND is still active.
IND	_____	
DMF	_____	Letter of authorization for FDA access dated 05-AUG-98. Date of last review: 27-MAY-99.
DMF	_____	Letter of authorization for FDA access dated 08-OCT-99. Date of last review: 19-JAN-00.
DMF	_____	Letter of authorization dated 14-AUG-98. Date of last review: 12-APR-95.
DMF	_____	Letter of authorization for FDA access 10-NOV-97. Date of last review: 24-AUG-98.
DMF	_____	Letter of authorization for FDA access: 28-AUG-98. Date of last review: 26-AUG-93; updated 13-MAY-94 and 01-JUN-95. Updates do not contain new significant information; review unnecessary; date of last formal review remains: 26-AUG-93.
DMF	_____	Letter of authorization dated: 10-FEB-98. Date of last review: 08-MAY-95.
DMF	_____	Letter of authorization for FDA access: 25-JUN-98. Date of last review: 20-SEP-96.

RELATED DOCUMENTS: None

CONSULTS: OPDRA; Microbiology

REMARKS/COMMENTS:

Section 9A, Stability Protocol:
Section 9D, Photostability:

Information Request

CONCLUSIONS & RECOMMENDATIONS:

The application is recommended for APPROVAL under section 505 of the FFD&C Act.

/S/

William C. Timmer, Ph.D.
Review Chemist, HFD-540/830

/S/

Wilson H. DeCamp, Ph.D.
Chemistry Team Leader, HFD-540/830

6/5/00

cc:

Original NDA 21-108

HFD-540/Division File
HFD-540/DD/JWilkin
HFD-540/Chem/WCTimmer
HFD-540/ChemTL/WHDeCamp
HFD-540/PM/OCintron
HFD-540/MO-TL/SWalker
HFD-540/MO/MLuke
HFD-540/Pharm-TL/AJacobs
HFD-540/Pharm/ANostrandt
HFD-540/Biopharm/EDBashaw
HFD-725/Stat/SThompson
HFD-725/Stat-TL/MAlosh
HFD-160/Micro/NSweeney
File Name: nda21108_org.doc

APPEARS THIS WAY
ON ORIGINAL

/S/ 2/16/00