

CLINICAL TEST AUTHORIZATION

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FOR
ADULT POWDERING STUDYTO
REQUESTING MANAGER
G. LEEPROJECT
NUMBER

2636.01

CTA NO.
6429.12DATE
1/10/77

OBJECTIVE(S) OF CLINICAL STUDY (REASON(S) FOR AND/OR POINT(S) TO BE PROVEN BY STUDY)
Assessment of whole body powdering of adults with JOHNSON'S Baby Powder #499
following showering.

PREPARATION TO BE TESTED (NAME, FORMULA NO., STRENGTH OR CONC. SIZE)

JOHNSON'S Baby Powder #499

QUANTITY AND DESCRIPTION OF TEST PREPARATION (IF APPLICABLE, INCLUDE CONCENTRATION, TYPE OF CONTAINER AND CONTENT)
(22) 9 oz. containers from the same lot, aged for at least 5 months at room temperature.

PREPARATION(S) TO BE EMPLOYED FOR CONTROL

NOT FOR 1 MONTH AT 100°

☒ NONE ☐

QUANTITY AND DESCRIPTION OF CONTROL PREPARATION(S) (IF APPLICABLE, INCLUDE CONCENTRATION, TYPE OF CONTAINER AND CONTENT)

THERAPY FACTORS (DOSE(S), FREQ. & DURATION)

As per protocol

STUDY
DESIGN☐ Uncontrolled ☐ Randomized
☐ Single Blind ☐ Crossover
☐ Double Blind ☒ Controlled

CLARIFY STUDY DESIGN ENTRIES (IF NECESSARY)

As per protocol

SPECIAL
STUDY
CONSID-
ERATIONSTYPE POPULATION ☐ Inpatient
☒ Outpatient ☐ SubjectsNO. OF PATIENTS/SUBJECTS
Test Prep.: 20 Controls: SameSEX RESTRICTION(S)
☐ Male Only ☐ Female Only ☒ MixedAGE RESTRICTION(S)
☐ NO ☒ YES Limits: AdultsCONTRAINDICATION CONDITION(S), HISTORY AND/OR
CONCOMITANT THERAPY TO BE AVOIDED

As per protocol

CONDITION/DISEASE AND/OR DIAGNOSIS REQ'D. FOR STUDY

As per protocol

MEDICAL
HISTORY,
PHYSICAL
EXAM
AND/OR
LAB DATA
REQ'D.

DETAIL (HISTORY INFO., PHYSICAL EXAM, SPECIAL EMPHASIS, AND LAB WORK - CBC, URINALYSIS, SMA-12, ETC.) INDICATE FREQ.

As per protocol

Study
Restrictions
& Specifi-
cations to
be metCOMPLETION DATE
ASRP

TOTAL EXP. LIMIT

\$ -

FOA STATUS

☒ None ☐ Ind. To Be Filed ☐ Ind. Filed

PROTOCOL FORMAT REQUIRED

☐ 1572 ☐ 1573 ☒ N/A

THIS AUTHORIZATION IS

☐ NEW ☐ Has no effect on Previous Auth.☒ Supplements ☐ Supersedes
☐ Amends

Previous Authorization No. 4929, 4303, 5256

COMMENTS

PROPOSED LABEL FOR TEST PREPARATION

JOHNSON & JOHNSON
Department of Clinical Research, New Brunswick, N.J.

PROPOSED LABEL FOR CONTROL PREPARATION

JOHNSON & JOHNSON
Department of Clinical Research, New Brunswick, N.J.

Control #

9 oz.

Product JOHNSON'S Baby Powder #499

For Investigational use only
JOHNSON & JOHNSON
Baby Products Company
Medical & Regulatory Affairs
U. S. Route 202
Paritan, N. J. 08869

CRA SIGNATURE / DIRECTOR-CLIN. RES. SIGNATURE DATE

MANAGER-REG. AFFAIRS SIGNATURE

APPROVAL DATE