CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215272Orig1s000

<u>LABELING</u>

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use VTAMA® cream safely and effectively. See full prescribing information for VTAMA.

VTAMA (tapinarof) cream, for topical use
Initial U.S. Approval: 2022

----------INDICATIONS AND USAGE----------
VTAMA cream, 1% is an-aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults. (1)

----------DOSAGE AND ADMINISTRATION----------
- Apply a thin layer of VTAMA cream to affected areas once daily. (2)
- VTAMA cream is not for oral, ophthalmic, or intravaginal use. (2)

----------DOSAGE FORMS AND STRENGTHS----------
Cream, 1% (3)
Each gram of VTAMA cream contains 10 mg of tapinarof. (3)

----------CONTRAINDICATIONS----------
None. (4)

----------ADVERSE REACTIONS----------
Most common adverse reactions (incidence ≥ 1%) in subjects treated with VTAMA cream were folliculitis, nasopharyngitis, contact dermatitis, headache, pruritus, and influenza. (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Dermavant Sciences, Inc. at 1-8DERMAVANT or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 5/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

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*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

VTAMA® (tapinarof) cream, 1% is an aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults.

2 DOSAGE AND ADMINISTRATION

Apply a thin layer of VTAMA cream to affected areas once daily.

Wash hands after application, unless VTAMA cream is for treatment of the hands.

VTAMA cream is not for oral, ophthalmic, or intravaginal use.

3 DOSAGE FORMS AND STRENGTHS

Cream, 1%

Each gram of VTAMA cream contains 10 mg of tapinarof in a white to off-white cream.

4 CONTRAINDICATIONS

None.

6 ADVERSE REACTIONS

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In two randomized, double-blind, multicenter, vehicle-controlled clinical trials (PSOARING 1 and PSOARING 2), 1025 adults with plaque psoriasis were treated with VTAMA cream or vehicle cream once daily for up to 12 weeks.

Subjects ranged in age from 18 to 75 years, with an overall median age of 51 years. The majority of subjects were white (85%) and male (57%); and 85% were non-Hispanic or Latino.

Table 1 presents adverse reactions that occurred in at least 1% of subjects treated with VTAMA cream, and for which the rate exceeded the rate for vehicle.

Table 1: Adverse Reactions Occurring in ≥1% of the Subjects in the 12-week PSOARING 1 and PSOARING 2 Clinical Trials

Adverse Reaction	VTAMA cream N=683 n (%)	Vehicle cream N=342 n (%)
Folliculitis[a]	140 (20)	3 (1)
Nasopharyngitis[b]	73 (11)	31 (9)
Contact dermatitis[c]	45 (7)	2 (1)
Headache[d]	26 (4)	5 (1)

Pruritus[e]	20 (3)	2 (1)
Influenza[f]	14 (2)	2 (1)

[a] Folliculitis includes application site folliculitis and folliculitis
[b] Nasopharyngitis includes nasopharyngitis, nasal congestion, pharyngitis, respiratory tract infection (RTI) viral, rhinorrhea, sinus congestion, upper RTI, and viral upper RTI
[c] Contact dermatitis includes dermatitis, contact dermatitis, hand dermatitis, and rash
[d] Headache includes headache, migraine, and tension headache
[e] Pruritus includes application site pruritus, pruritus, generalized pruritus, and genital pruritus
[f] Influenza includes influenza and influenza-like illness

Two (0.3%) subjects using VTAMA cream developed urticaria. Adverse reactions leading to treatment discontinuation in >1% of subjects who received VTAMA cream were contact dermatitis (2.9%) and folliculitis (2.8%).

In an open label safety trial (PSOARING 3), 763 subjects were treated for up to an additional 40 weeks after completing PSOARING 1 or PSOARING 2. In addition to the adverse reactions reported in the 12-week PSOARING 1 and PSOARING 2 clinical trials, the following adverse reactions were reported: urticaria (1.0%) and drug eruption (0.7%).

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

The available data on VTAMA cream use in pregnant women are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes. In animal reproduction studies, subcutaneous administration of tapinarof to pregnant rats and rabbits during the period of organogenesis resulted in no significant adverse effects at doses 268 and 16 times, respectively, the maximum recommended human dose (MRHD) (*see Data*).

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of major birth defects, loss, and other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Data

Animal Data

In an embryofetal development study in rats, tapinarof was administered by subcutaneous injection to pregnant animals at doses of 1.2, 6.9 and 34 mg/kg/day during the period of organogenesis. Tapinarof was not associated with embryofetal lethality or fetal malformations. Tapinarof increased the incidence of skeletal variations (incomplete ossification of nasal bones) at the dose of 34 mg/kg/day (268 times the MRHD based on AUC comparisons).

In an embryofetal development study in rabbits, tapinarof was administered by subcutaneous injection to pregnant animals twice daily at doses of 0.3, 1, and 3 mg/kg/day during the period of organogenesis. Maternal toxicity as evidenced by decreased maternal body weight gain and associated increased post-implantation loss (embryolethality) was observed at 3 mg/kg/day. In addition, fetal skeletal variations were observed at 3 mg/kg/day. Tapinarof was not associated with embryofetal lethality or fetal malformations at doses up to 1 mg/kg/day (16 times the MRHD based on AUC comparison) or fetal malformations at doses up to 3 mg/kg/day (30 times the MRHD based on AUC comparison).

In a second embryofetal development study in rabbits, tapinarof was administered by continuous subcutaneous infusion to pregnant animals at doses of 1, 2 and 3 mg/kg/day during the period of organogenesis. Tapinarof was not associated with embryofetal lethality or fetal malformations at doses up to 3 mg/kg/day (20 times the MRHD based on AUC comparison).

In a prenatal and postnatal development study, tapinarof was administered by subcutaneous injection to pregnant rats at doses of 1, 6 and 30 mg/kg/day beginning on gestation day 6 through lactation day 20. Maternal toxicity associated with decreases in body weight gain and food consumption was noted at 30 mg/kg/day (268 times the MRHD based on AUC comparisons). Tapinarof decreased fetal survival and viability that resulted in reduced litter sizes and decreased fetal weights at doses greater than or equal to 6 mg/kg/day (45 times the MRHD based on AUC comparisons). No tapinarof-related effects on fetal survival and viability were noted at a dose of 1 mg/kg/day (6 times the MRHD based on AUC comparisons). No tapinarof-related effects on postnatal development, neurobehavioral or reproductive performance of offspring were noted at doses up to 30 mg/kg/day (268 times the MRHD based on AUC comparison).

8.2 Lactation

Risk Summary

No data are available regarding the presence of tapinarof in human milk or the effects of tapinarof on the breastfed infant, or on milk production. Tapinarof was detected in rat offspring following subcutaneous administration to pregnant female rats which suggests that tapinarof was transferred into the milk of lactating rats *(see Data)*. When a drug is present in animal milk, it is likely that the drug will be present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VTAMA cream and any potential adverse effects on the breastfed infant from VTAMA cream or from the underlying maternal condition.

Data

In a prenatal and postnatal development study, tapinarof was administered by subcutaneous injection to pregnant rats at doses of 1, 6, and 30 mg/kg/day from gestation day 6 through lactation day 20. Tapinarof was quantifiable in offspring plasma samples on postnatal day 10 at doses of 6 and 30 mg/kg/day, suggesting that tapinarof is present in animal milk.

8.4 Pediatric Use

Safety and efficacy of VTAMA cream have not been established in pediatric subjects with psoriasis under 18 years of age.

Juvenile Animal Toxicity Data

In a juvenile animal toxicity study, tapinarof was administered by subcutaneous injection to juvenile rats at doses of 1, 10 and 20 mg/kg/day from postnatal day (PND) 7 to 21 and at doses of 1.5, 15, and 30 mg/kg/day from PND 22 to 77. The dose escalation conducted at PND 22 was implemented to maintain consistent systemic exposure across the duration of the dosing period. Renal pelvic dilatation was observed at doses greater than or equal to 15 mg/kg/day (165 times the MRHD based on AUC comparisons). No adverse effects in juvenile animals were noted at 1.5 mg/kg/day (11 times the MRHD based on AUC comparisons).

8.5 Geriatric Use

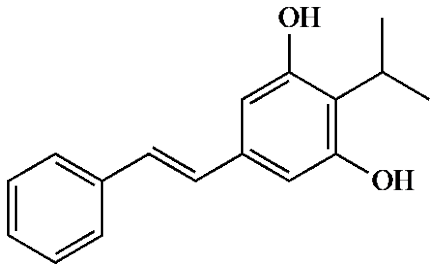
Of the 683 subjects exposed to VTAMA cream in the PSOARING 1 or PSOARING 2 clinical trials, 99 (14.5%) were 65 years of age and older, including 8 (1.2%) subjects who were 75 years of age and older. No overall

differences in efficacy, safety, or tolerability were observed between elderly subjects and younger adult subjects in clinical trials.

11 DESCRIPTION

VTAMA (tapinarof) cream contains tapinarof as the active ingredient. Tapinarof is an aryl hydrocarbon receptor agonist.

Tapinarof is a white to pale brown powder. Chemically, tapinarof is 3, 5-dihydroxy-4-isopropyl-*trans*-stilbene, also known as (E)-2-isopropyl-5-styrylbenzene-1,3-diol, with the empirical formula $C_{17}H_{18}O_2$, a molecular weight of 254.32, and the following structural formula.



Each gram of VTAMA cream for topical use contains 10 mg of tapinarof in a white to off-white cream. VTAMA cream also contains the following inactive ingredients: benzoic acid, butylated hydroxytoluene, citric acid monohydrate, diethylene glycol monoethyl ether, edetate disodium, emulsifying wax, medium-chain triglycerides, polyoxyl 2 stearyl ether, polyoxyl 20 stearyl ether, polysorbate 80, propylene glycol, purified water, and sodium citrate dihydrate.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Tapinarof is an aryl hydrocarbon receptor (AhR) agonist. The specific mechanisms by which VTAMA cream exerts its therapeutic action in psoriasis patients are unknown.

12.2 Pharmacodynamics

Pharmacodynamics of VTAMA cream are unknown.

Cardiac Electrophysiology

At the approved recommended dosage, VTAMA does not prolong the QTc interval to any clinically relevant extent.

12.3 Pharmacokinetics

Absorption

No accumulation was observed with repeat topical application. Plasma concentration of tapinarof was below the quantifiable limits (BQL) of the assay (lower limit of quantification was 50 pg/mL) in 68% of the pharmacokinetic samples. On Day 1, mean ± SD values of C_{max} and $AUC_{0\text{-last}}$ were 0.90 ± 1.4 ng/mL and 4.1 ± 6.3 ng.h/mL, respectively, following a mean daily dose of 5.23 g applied to a mean body surface area involvement of 27.2% (range 21 to 46%) in 21 subjects with moderate to severe plaque psoriasis. On Day 29, the mean ± SD C_{max} and $AUC_{0\text{-last}}$ were 0.12 ± 0.15 ng/mL and 0.61 ± 0.65 ng.h/mL, respectively.

Distribution

Human plasma protein binding of tapinarof is approximately 99% *in vitro*.

Elimination

Metabolism

Tapinarof is metabolized in the liver by multiple pathways including oxidation, glucuronidation, and sulfation *in vitro.*

Drug Interaction Studies

In Vitro Studies

Cytochrome P450 (CYP) Enzymes: Tapinarof is not an inhibitor of CYP2B6, CYP2C8, CYP2C9, CYP2C19, CRP2D6 or CYP3A4/5. Tapinarof is not an inducer of CYP1A2, CYP2B6 or CYP3A4.

Transporter Systems: Tapinarof is not an inhibitor of BCRP, MATE1, MATE-2K, OAT1, OAT3, OATP1B1, OATP1B3, OCT1, OCT2, or P-gp. Tapinarof is not a substrate for BCRP, OATP1B1, OATP1B3, or P-gp.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term carcinogenicity studies were conducted in mice (daily topical administration at doses of 0.5, 1.5 and 3% tapinarof cream) and in rats (subcutaneous administration at doses of 0.1, 0.3, and 1 mg/kg/day tapinarof). No drug-related neoplasms were noted in mice after 98 (females) to 102 (males) weeks of daily topical administration at doses up to 3% tapinarof cream (44 times the MRHD based on AUC comparisons). No drug-related neoplasms were noted in female rats after 83 weeks of daily subcutaneous administration at doses up to 1 mg/kg/day tapinarof (9 times the MRHD based on AUC comparisons).

Tapinarof revealed no evidence of mutagenicity or clastogenicity in an Ames assay, an in vitro mammalian chromosomal aberration assay, an in vitro mouse lymphoma assay and two in vivo micronucleus-assays in mice and rats.

Tapinarof did not impair female fertility at subcutaneous doses up to 30 mg/kg/day (268 times the MRHD based on AUC comparisons).

14 CLINICAL STUDIES

Two multicenter, randomized, double-blind, vehicle-controlled trials were conducted to evaluate the safety and efficacy of VTAMA cream for the treatment of adults with plaque psoriasis (PSOARING 1 [NCT03956355] and PSOARING 2 [NCT03983980]). These trials were conducted in a total of 1025 subjects randomized 2:1 to VTAMA cream or vehicle cream applied once daily for 12 weeks to any lesion regardless of anatomic location.

Baseline disease severity was graded using the 5-point Physician's Global Assessment (PGA). The majority of subjects had "Moderate" disease (82%), while 10% had "Mild" disease, and 8% had "Severe" disease at baseline. The extent of disease involvement assessed by mean body surface area (BSA), excluding the scalp, palms, and soles, was 8% (range 3 to 20%). Subjects ranged in age from 18 to 75 years, with a median age of 51 years. Overall, 57% of the subjects were male and 85% were White.

The primary efficacy endpoint in both studies was the proportion of subjects who achieved treatment success, defined as a PGA score of "Clear" (0) or "Almost Clear" (1) and at least a 2-grade improvement from baseline. Efficacy results from the two trials are summarized in Table 2.

Table 2: Clinical Response at Week 12 in PSOARING 1 and PSOARING 2 in Adults with Plaque Psoriasis (Intent-to-Treat; Multiple Imputation)				
	PSOARING 1		PSOARING 2	
Clinical Response	VTAMA cream N=340	Vehicle cream N=170	VTAMA cream N=343	Vehicle cream N=172
PGA Treatment Success [a]	36%	6%	40%	6%
Difference (95% CI)	29% (22%, 36%)		34% (27%, 41%)	

[a] Treatment success was defined as a PGA score of "Clear" or "Almost Clear" and at least a 2-grade improvement from baseline.

Following 12 weeks of treatment, 73 subjects randomized to VTAMA achieved complete disease clearance (PGA 0) and had VTAMA withdrawn. These subjects were followed for up to 40 additional weeks with a median time to first worsening (PGA ≥ 2 ["Mild"]) of 114 days (95% CI: 85, 142).

16 HOW SUPPLIED/STORAGE AND HANDLING

VTAMA (tapinarof) cream, 1% is a white to off-white cream. Each gram of VTAMA cream contains 10 mg of tapinarof. It is supplied in the following size:

60 g laminated tubes: NDC 81672-5051-1

Storage and Handling:

- Store at 20°C to 25°C (68°F to 77°F) with excursions permitted between 15°C and 30°C (59°F and 86°F).
- Do not freeze.
- Protect from exposure to excessive heat.
- Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Administration Instructions

- Apply VTAMA cream once daily to psoriasis skin lesions only and avoid unaffected areas of skin.
- Wash hands after application unless VTAMA cream is for treatment of the hands.
- Advise patients that VTAMA cream is for external use only.

Marketed by:
Dermavant Sciences Inc., 3780 Kilroy Airport Way, Long Beach, CA 90806

VTAMA is a registered trademark of Dermavant Sciences, GmbH or its affiliates.
U.S. Patents: www.dermavant.com/patents

PATIENT INFORMATION
VTAMA® (Vee-TAM-uh)
(tapinarof)
cream, for topical use

Important information: VTAMA cream is for use on the skin (topical use) only. Do not use VTAMA cream in your eyes, mouth, or vagina.

What is VTAMA cream?

VTAMA cream is a prescription medicine used on the skin (topical) to treat plaque psoriasis in adults.

It is not known if VTAMA cream is safe and effective in children with psoriasis under 18 years of age.

Before using VTAMA cream, tell your healthcare provider about all of your medical conditions, including if you:

- are pregnant or plan to become pregnant. It is not known if VTAMA cream will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if VTAMA cream passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with VTAMA cream.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How should I use VTAMA cream?

- Use VTAMA cream exactly as your healthcare provider tells you to use it.
- Apply a thin layer of VTAMA cream only to your psoriasis skin lesions 1 time a day. Avoid applying VTAMA cream to unaffected areas of your skin.
- Wash your hands after applying VTAMA cream unless you are using it to treat your hands.
- If someone else applies VTAMA cream for you, they should wash their hands after application.

What are the possible side effects of VTAMA cream?

The most common side effects of VTAMA cream include:

- red raised bumps around the hair pores (folliculitis)
- pain or swelling in the nose and throat (nasopharyngitis)
- skin rash or irritation including itching and redness, peeling, burning, or stinging
- headache
- itching
- flu

These are not all the possible side effects of VTAMA cream.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store VTAMA cream?

- Store VTAMA cream at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not freeze VTAMA cream.
- Protect VTAMA cream from exposure to excessive heat.
- Keep VTAMA cream and all medicines out of the reach of children.

General information about the safe and effective use of VTAMA cream.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use VTAMA cream for a condition for which it was not prescribed. Do not give VTAMA cream to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about VTAMA cream that is written for health professionals.

What are the ingredients in VTAMA cream?

Active ingredient: tapinarof

Inactive ingredients: benzoic acid, butylated hydroxytoluene, citric acid monohydrate, diethylene glycol monoethyl ether, edetate disodium, emulsifying wax, medium-chain triglycerides, polyoxyl 2 stearyl ether, polyoxyl 20 stearyl ether, polysorbate 80, propylene glycol, purified water, and sodium citrate dihydrate.

Marketed by: Dermavant Sciences Inc., 3780 Kilroy Airport Way, Long Beach, CA 90806
For more information, go to www.VTAMA.com or call 1-8DERMAVANT
U.S. Patents: www.dermavant.com/patents
VTAMA is a registered trademark of Dermavant Sciences, GmbH or its affiliates.

This Patient Informa ion has been approved by the U.S. Food and Drug Administration. Issued: 5/2022

(b) (4)

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Not for oral, ophthalmic, or intravaginal use.

Recommended Dosage: See prescribing information.

Each gram contains: Active ingredient: tapinarof 10 mg (1%); **Inactive ingredients:** benzoic acid, butylated hydroxytoluene, citric acid monohydrate, diethylene glycol monoethyl ether, edetate disodium, emulsifying wax, medium-chain triglycerides, polyoxyl 2 stearyl ether, polyoxyl 20 stearyl ether, polysorbate 80, propylene glycol, purified water, and sodium citrate dihydrate.

Storage: Store at Controlled Room Temperature; 20 – 25°C (68 – 77°F); excursions permitted to 15 – 30°C (59 – 86°F). Do not freeze. Protect from exposure to excessive heat.
See back panel for lot number and expiration date

VTAMA®
(tapinarof) cream 1%

NDC 81672–5051–1
Rx only

For topical use only.

60g

VTAMA®
(tapinarof) cream 1%

NDC 81672–5051–1
Rx only

For topical use only.

60g

Pharma Code Ref No. 5353

6200000078601

Pharma Code Ref No. 5353

VTAMA®
(tapinarof) cream 1%
60g

GTIN- 00381672505117

S/N
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dermavant®
Marketed by:
Dermavant Sciences, Inc.
Long Beach, CA 90806
Product of Ireland

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Recommended Dosage: See prescribing information.

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(tapinarof) cream 1%

NDC 81672–5051–1
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Pharma Code Ref No. 5353

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62000000078601

VTAMA®
(tapinarof) cream 1%

60g

GTIN- 00381672505117

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NDC 81672–5051–1

Rx only

VTAMA®

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Storage: Store at Controlled Room Temperature; 20 – 25°C (68 – 77°F); excursions permitted to 15 – 30°C (59 – 86°F). Do not freeze. Protect from exposure to excessive heat.

See crimp end for lot code and expiration date.

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Long Beach, CA 90806
Product of Ireland

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LOT XXXX EXP MMM YYYY

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Pharma code Ref. No. 7923
Miniature

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Pharma code Ref. No. 7923
Miniature

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Pharma code Ref. No. 7923
Miniature

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Pharma code Ref. No. 7923
Miniature

(b) (4)

(b) (4)

VTAMA®
(tapinarof) cream 1%

NDC 81672-5051-02
Rx only
Sample – Not for Sale

For topical use only. 2g

Recommended Dosage:
See prescribing information

dermavant®
Marketed by: Dermavant Sciences, Inc.
Long Beach, CA 90806
Product of Ireland
See crimp end for lot code and expiration date.

620000000071206

LOT XXXX EXP MMM YYYY

Pharma code Ref. No. 515
miniature

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JULIE G BEITZ
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