RonanRx
PERSONALIZED MEDICINE

CLINICAL MONOGRAPH · NEURO & COGNITIVE (UNDER FDA REVIEW)

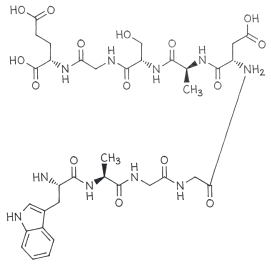
DSIP, Delta Sleep-Inducing Peptide

Sleep-related peptide under FDA review with physician-request review

Delta Sleep-Inducing Peptide, or DSIP, is a tiny 9-amino-acid peptide first isolated in 1977 by Swiss researchers Schoenenberger and Monnier from the cerebral venous blood of rabbits placed in deep slow-wave sleep [schoenenberger1977_pnas; schoenenberger1977_pflugers; kovalzon2006_riddle]. It got its name because injecting the peptide into other rabbits appeared to increase the slow-wave (delta) activity on their brain recordings.

Through the 1980s and into the early 1990s, a series of small European clinical trials tested DSIP in insomnia, narcolepsy, opioid and alcohol withdrawal, and chronic pain. Results were modest or mixed, the trials were small, and a clear pharmacological role for DSIP in human sleep regulation was never established. Most clinical development was abandoned by the late 1990s, and a 2006 review fittingly called DSIP 'a still unresolved riddle.'

DSIP has no FDA approval in the United States. This ingredient is part of an evolving FDA review process. Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case, and availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance.



EVIDENCE POSTURE PRECLINICAL EMERGING

REVIEWED **2026-05-11**


State-licensed 503A


Pharmacist reviewed


Doctor led


Cold-chain ready


Patient choice preserved

Contents

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FOR CLINICIANS

DSIP is a nonapeptide (Trp-Ala-Gly-Gly-Asp-Ala-Ser-Gly-Glu) characterized in 1977 by Schoenenberger and Monnier as a low-molecular-weight delta-EEG-enhancing factor purified from cerebral venous blood of rabbits in electrically induced slow-wave sleep [schoenenberger1977_pnas, schoenenberger1977_pflugers, monnier1977_synthetic]. Synthetic DSIP crosses the blood-brain barrier [monnier1977_bbb, banks2015_bbb_review] but the receptor, binding-site identity, and endogenous physiologic role have never been definitively established; a 2006 review in J Neurochem characterized DSIP as 'a still unresolved riddle' [kovalzon2006_riddle].

The clinical literature consists almost entirely of small uncontrolled or single-center European trials from the 1980s and 1990s. In insomnia, Schneider-Helmert reported partial normalization of sleep architecture in middle-aged and elderly chronic insomniacs [schneiderhelmert1986_efficacy, schneiderhelmert1987_24h] and modest effects in phase-shifted insomnia [schneiderhelmert1987_phaseshift]; an open trial in narcolepsy showed limited benefit [schneiderhelmert1984_narcolepsy]. A 1992 double-blind trial in chronic insomnia (Bes et al., Neuropsychobiology, N=16) did not demonstrate convincing efficacy on polysomnographic endpoints [bes1992_insomnia]. In withdrawal syndromes, an open study reported subjective benefit during alcohol and opiate detoxification [dick1984_withdrawal] [dick1984_withdrawal]; Soyka and Rothenhaeusler (1997, Am J Psychiatry) and Backmund et al. (1998, J Clin Psychopharmacol) reported short, open-label trials of DSIP for opioid detoxification with mixed results [soyka1997_opioid, backmund1998_opioid]. A pilot study reported analgesic adjunct effects in chronic-pain patients [larbig1984_pain]. None of this corpus advanced to a registration-quality phase 3 program; reviews in 2001 and 2006 emphasized the absence of a coherent mechanism, the inconsistency of effect, and the abandonment of clinical development [pollard2001_review, kovalzon2006_riddle].

DSIP has no FDA approval in the United States. This ingredient is part of an evolving FDA review process. Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case, and availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance.

Why Personalized DSIP, Delta Sleep-Inducing Peptide

The evidence base for DSIP is old and uneven. Early studies explored sleep architecture, stress response, opioid withdrawal, and neurologic symptoms, but the literature does not provide a modern, FDA-reviewed clinical dosing or safety program.

Physicians may submit patient-specific prescription requests for DSIP for pharmacy review. Certain preparations may be available now when clinically appropriate, lawfully prescribed, supported by patient-specific documentation, and approved by the dispensing pharmacy. Availability is determined case by case. This is not a consumer access promise; it is a clinical, sourcing, formulation, and regulatory review process. FDA has scheduled emideltide, also referred to as DSIP, for discussion at the 23-24 Jul 2026 Pharmacy Compounding Advisory Committee meeting.

A regulated request for DSIP starts with a clinician and an identified patient. It does not start with a consumer selecting a sleep peptide from a research-use-only marketplace.

Quick Facts About DSIP, Delta Sleep-Inducing Peptide

Category: Endogenous nonapeptide (Trp-Ala-Gly-Gly-Asp-Ala-Ser-Gly-Glu); historically studied as a sleep-related neuropeptide

Active ingredient: Delta Sleep-Inducing Peptide (DSIP), a 9-amino-acid peptide originally isolated from cerebral venous blood of rabbits induced into electrically stimulated slow-wave sleep

FDA-approved branded forms: None. There is no FDA-approved product containing DSIP for any indication.

Route: Intravenous and subcutaneous in the European clinical literature of the 1980s; intranasal and other routes explored preclinically. No labeled or compendial route exists.

Evidence posture: Small European clinical trials in chronic insomnia, narcolepsy, opioid detoxification, alcohol/opiate withdrawal, and chronic pain published 1984, 1998. Effect sizes were modest or inconsistent, samples were small, and clinical development was largely abandoned by the late 1990s. Modern peer-reviewed work is dominated by preclinical rodent studies of stress, stroke, and neuroprotection.

FDA-approval status: Category 2, evolving FDA review process. Valid patient-specific prescription required; supporting clinical rationale may be requested.

Compounded under: Not currently compounded by RonanRx. DSIP is a research peptide that has not cleared the safety review required for 503A patient-specific compounding under the FDA's interim bulks framework. This brief documents the substance for awareness; it is not a buying guide.

Important compounding caution: Physicians may submit patient-specific prescription requests for pharmacy review. Availability is determined case by case.

> **SPECIALS: PATIENT-SPECIFIC PRESCRIPTION ONLY**
>
> Physicians may submit patient-specific prescription requests for DSIP, Delta Sleep-Inducing Peptide for pharmacy review. Certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case.
>
> - **Made to order, not off a shelf.** No batch sits in a warehouse waiting for buyers. Your prescription triggers the prep.
> - **Named-patient label.** The bottle carries one patient's name. The batch records carry one prescription.
> - **Dose, strength, and route chosen for the patient.** A prescriber decides what gets compounded, not a manufacturer who set the strength for a trial population.
> - **Licensed pharmacist on the hook.** A real person, with a license that can be pulled, signs off on every prep. State inspectors check the facility.
> - **Compounded drugs are not FDA-approved.** They should not be evaluated using branded-drug trial data alone. Availability varies by state and prescribed medication.

How This Differs from a Research-Use-Only Website

A research-use-only website ships a vial from a warehouse. There is no prescription, no pharmacist, no facility inspection, and no way to recall the product if something is wrong with it. If the vial is mislabeled, contaminated, or under-potent, there is nobody whose license is at stake.

A 503A compounding pharmacy is the other thing. The doctor writes the prescription. A licensed pharmacist, whose name is on the label, prepares the medicine in a facility the state inspects. If something goes wrong, there is a person and a license on the hook, and a documented chain of custody on every lot. That accountability is what makes it safe.

What is DSIP, Delta Sleep-Inducing Peptide?

Delta Sleep-Inducing Peptide (DSIP) is a 9-amino-acid peptide with the sequence Trp-Ala-Gly-Gly-Asp-Ala-Ser-Gly-Glu [graf1987_pineal_nat; kovalzon2006_riddle]. It was first isolated by Schoenenberger and colleagues in Basel from the cerebral venous blood of rabbits whose intralaminar thalamic nuclei had been electrically stimulated to induce slow-wave sleep [schoenenberger1977_pnas, schoenenberger1977_pflugers]. Recipient rabbits dialyzed against blood from sleep-induced donors developed increased delta-band EEG activity, the observation that named the peptide.

Synthetic DSIP, prepared shortly after the natural peptide was sequenced, reproduced some of the EEG effects of the natural material in animals and showed measurable transport across the blood-brain barrier

[monnier1977_synthetic, monnier1977_bbb]. The peptide and its phosphorylated form (P-DSIP) were later identified by immunoreactivity in cerebrospinal fluid and pineal gland, but specific receptors, binding partners, and an endogenous physiological role were never definitively established [ernst1987_csf; noteborn1988_pineal].

There is no FDA-approved product containing DSIP for any indication. There is no USP monograph. DSIP is not listed on the FDA Category 1 bulks list for 503A use; it falls within the broader category of investigational peptides under FDA scrutiny [fda_category2_bulks, fda503a]. Material sold today is sourced from research-peptide suppliers and is not produced under the identity, sterility, and stability standards required of compounded sterile preparations.

How DSIP, Delta Sleep-Inducing Peptide Works

A coherent mechanism of action for DSIP has never been established. The original observation was bioassay-based: dialysate from sleep-induced rabbits enhanced delta-band EEG activity in recipient animals, and a peptide fraction with that activity was purified, sequenced, and synthesized [schoenenberger1977_pnas, schoenenberger1977_pflugers, monnier1977_synthetic]. The receptor target for DSIP and its principal physiological pathway have not been identified in the peer-reviewed literature [pollard2001_review, kovalzon2006_riddle] [graf1982_neurotransmitters].

Reported pharmacological effects in rodent and rabbit studies include modulation of delta-frequency EEG, interactions with adrenergic and serotonergic neurotransmission, effects on pineal N-acetyltransferase activity, and modest temperature effects [graf1987_pineal_nat; tsunashima1994_temperature]. These effects are heterogeneous across labs and have not been integrated into a mechanism-of-action framework that predicts a clinical effect in humans.

DSIP crosses the blood-brain barrier, as characterized in the original rabbit transport studies and in later reviews of peptide transport [monnier1977_bbb, banks2015_bbb_review] [scherschlicht1984_pharm]. BBB permeability is a necessary but not sufficient condition for a centrally-acting therapeutic; without a defined receptor and pathway, the relevance of BBB transport to clinical effect remains unresolved.

Detailed Mechanism of DSIP, Delta Sleep-Inducing Peptide

DSIP was identified by a classical 'donor-recipient' transfer paradigm: cerebral venous blood from rabbits in electrically induced slow-wave sleep, dialyzed against blood of an awake recipient rabbit, transferred a delta-EEG-enhancing factor. Schoenenberger and Monnier's PNAS report (1977) characterized that factor as a low-molecular-weight peptide; the Pflugers Arch report (1977) reported final isolation, sequencing, and bioassay validation [schoenenberger1977_pnas, schoenenberger1977_pflugers]. Synthetic DSIP was characterized in Experientia by Monnier et al. (1977) as biologically equivalent to the natural peptide, and

BBB transport was demonstrated in rabbit using radio-labeled material [monnier1977_synthetic, monnier1977_bbb].

Subsequent rodent work probed neurotransmitter and neuroendocrine effects. Graf and colleagues (1982, 1987) reported DSIP-induced changes in brain neurotransmitter concentrations and modulation of pineal N-acetyltransferase via the alpha-1-adrenergic receptor [graf1982_neurotransmitters, graf1987_pineal_nat]. Scherschlicht et al. (1984) summarized broader pharmacological characterization in animals, sleep effects, locomotor effects, and limited interactions with classical receptor classes [scherschlicht1984_pharm]. Tsunashima et al. (1994) showed that DSIP modulates body temperature responses to serotonergic agonists in rats [tsunashima1994_temperature]. Ernst et al. (1987) reported DSIP-like and P-DSIP-like immunoreactivity in human CSF across dementia, multi-infarct, hydrocephalus, and Parkinson's disease populations, without identifying a disease-specific pattern [ernst1987_csf]. Noteborn et al. (1988) purified DSIP-like material from ovine pineal glands suggesting endogenous distribution [noteborn1988_pineal].

Modern preclinical work has explored DSIP in stress and ischemia models. Tukhovskaya et al. (2021) reported preclinical efficacy of DSIP in a rat focal stroke model [tukhovskaya2021_stroke]. Bobyntsev et al. (2016) reported effects on hepatocyte function during restraint stress [bobyntsev2016_hepatocyte]. Engineering work has explored DSIP fused to protein-transduction-domain, HSA constructs and to Pichia pastoris-secreted carriers to improve delivery [zhang2017_fusion, mu2024_fusion]. None of this preclinical activity has translated to a registered human clinical-development program in the 2010s or 2020s [kovalzon2006_riddle, pollard2001_review].

DSIP, Delta Sleep-Inducing Peptide Research History

DSIP was discovered in 1977 by Guido A. Schoenenberger, Marcel Monnier, and colleagues at the University of Basel. The seminal report, 'Characterization of a delta-electroencephalogram (-sleep)-inducing peptide' (PNAS, March 1977), described isolation of a low-molecular-weight peptide from cerebral venous blood of rabbits in electrically induced slow-wave sleep that, when transferred to a recipient rabbit, enhanced delta-band EEG activity [schoenenberger1977_pnas]. The Pflugers Arch report later in 1977 documented final isolation, characterization, and activity testing [schoenenberger1977_pflugers], and Experientia papers by Monnier et al. reported synthesis of the nonapeptide and demonstrated blood-brain barrier transport [monnier1977_synthetic, monnier1977_bbb].

Through the early 1980s the Basel group and European collaborators characterized pharmacology in rodents [scherschlicht1984_pharm, graf1982_neurotransmitters]. A cluster of clinical reports in European Neurology in 1984 explored DSIP in insomnia (Schneider-Helmert), narcolepsy (Schneider-Helmert), withdrawal syndromes (Dick et al.), and chronic pain (Larbig et al.) [schneiderhelmert1984_insomnia; schneiderhelmert1984_narcolepsy; dick1984_withdrawal]. Schneider-Helmert followed with reports on chronic insomnia in older adults (Eur Neurol 1986) and on 24-hour sleep-wake behaviour in severe chronic

insomnia (Eur Neurol 1987), plus a German case-series report in phase-shifted insomnia [schneiderhelmert1986_efficacy, schneiderhelmert1987_24h, schneiderhelmert1987_phaseshift].

The 1992 double-blind trial by Bes et al. in Neuropsychobiology represented the most methodologically rigorous attempt to test DSIP in chronic insomnia and produced limited evidence of effect on polysomnographic endpoints [bes1992_insomnia]. In opioid detoxification, Soyka and Rothenhaeusler (1997, Am J Psychiatry) and Backmund et al. (1998, J Clin Psychopharmacol) reported open-label clinical trials with mixed results, after which clinical development effectively halted [soyka1997_opioid, backmund1998_opioid]. Review articles in 2001 (Pollard, Eur J Anaesthesiol) and 2006 (Kovalzon and Strekalova, J Neurochem) characterized DSIP as a substance of unresolved mechanism whose clinical promise had not been confirmed [pollard2001_review, kovalzon2006_riddle] [larbig1984_pain].

Modern peer-reviewed activity has been preclinical and modest in volume: rat stroke models [tukhovskaya2021_stroke], hepatocyte stress [bobyntsev2016_hepatocyte], and bioengineering work on DSIP fusion peptides for delivery [zhang2017_fusion, mu2024_fusion]. A 2026 orthopaedic-peptides review situates DSIP among investigational peptides without an established clinical role [rahman2026_orthopaedic]. DSIP has not appeared on the FDA Category 1 bulks list for 503A compounding [fda_category2_bulks].

DSIP, Delta Sleep-Inducing Peptide Timeline

- **1977** • Schoenenberger and Monnier (PNAS) characterize DSIP from cerebral venous blood of rabbits in electrically induced slow-wave sleep, the discovery paper [schoenenberger1977_pnas]
- **1977** • Schoenenberger et al [schoenenberger1977_pflugers]. (Pflugers Arch) report final isolation, characterization, and activity testing of the natural delta-EEG-enhancing nonapeptide
- **1977** • Monnier et al [monnier1977_synthetic; monnier1977_bbb]. (Experientia) demonstrate that synthetic DSIP reproduces the bioactivity of the natural peptide and crosses the blood-brain barrier in rabbits
- **1982** • Graf et al [graf1982_neurotransmitters]. (Pharmacol Biochem Behav) report DSIP-induced changes in daily concentrations of brain neurotransmitters and plasma proteins in rats
- **1984** • European Neurology cluster: Scherschlicht (pharmacology), Schneider-Helmert (insomnia, narcolepsy), Dick et al [scherschlicht1984_pharm; schneiderhelmert1984_insomnia; schneiderhelmert1984_narcolepsy]. (alcohol and opiate withdrawal), Larbig et al [dick1984_withdrawal; larbig1984_pain]. (chronic pain)
- **1986** • Schneider-Helmert (Eur Neurol), efficacy of DSIP to normalize sleep in middle-aged and elderly chronic insomniacs [schneiderhelmert1986_efficacy]

1987 • Schneider-Helmert (Eur Neurol), effects of DSIP on 24-hour sleep-wake behaviour in severe chronic insomnia [schneiderhelmert1987_24h]

1987 • Schneider-Helmert et al [schneiderhelmert1987_phaseshift]. (Dtsch Med Wochenschr), case-series report on DSIP in phase-shifted insomnia

1987 • Ernst et al [ernst1987_csf]. (J Neurol), DSIP and P-DSIP immunoreactivity in CSF across dementia, multi-infarct, hydrocephalus, and Parkinson's populations

1987 • Graf and Schoenenberger (J Neurochem), DSIP modulates rat pineal N-acetyltransferase via alpha-1-adrenergic receptor [graf1987_pineal_nat]

1988 • Noteborn et al [noteborn1988_pineal]. (J Pineal Res), purification of DSIP-like material from ovine pineal glands

1992 • Bes et al [bes1992_insomnia]. (Neuropsychobiology), double-blind trial of DSIP in chronic insomniac patients; limited evidence of polysomnographic effect

1994 • Tsunashima et al [tsunashima1994_temperature]. (Peptides), DSIP modulates body-temperature changes induced by serotonergic agonists in rats

1997 • Soyka and Rothenhaeusler (Am J Psychiatry), letter on DSIP in opioid detoxification [soyka1997_opioid]

1998 • Backmund et al [backmund1998_opioid]. (J Clin Psychopharmacol), open clinical trial of DSIP for opioid detoxification; clinical development largely abandoned after this point

2001 • Pollard and Pomfrett (Eur J Anaesthesiol) review of DSIP, emphasizes absence of established mechanism and inconsistency of clinical effect [pollard2001_review]

2006 • Kovalzon and Strekalova (J Neurochem), review titled 'Delta sleep-inducing peptide (DSIP): a still unresolved riddle' summarizes three decades of inconclusive work [kovalzon2006_riddle]

2015 • Banks (Peptides), review of peptides and the blood-brain barrier; DSIP cited among historically studied BBB-crossing peptides [banks2015_bbb_review]

2016 • Bobyntsev et al [bobyntsev2016_hepatocyte]. (Bull Exp Biol Med), DSIP effects on hepatocyte function in rats during restraint stress

2017 • Zhang et al [zhang2017_fusion]. (Protein Pept Lett), expression and purification of DSIP fused with protein transduction domain and human serum albumin in Pichia pastoris

2021 • Tukhovskaya et al [tukhovskaya2021_stroke]. (Molecules), DSIP recovers motor function in Sprague-Dawley rats after focal stroke (preclinical)

2024 • Mu et al [mu2024_fusion]. (Front Pharmacol), Pichia-secreted BBB-crossing peptides and a DSIP fusion peptide in PCPA-induced insomnia mouse models

2026 • Rahman et al [rahman2026_orthopaedic]. (JAAOS Glob Res Rev) orthopaedic therapeutic-peptides review, situates DSIP among investigational peptides without an established clinical role

Clinical Contexts for DSIP, Delta Sleep-Inducing Peptide

Chronic insomnia EMERGING

Studied in small uncontrolled and double-blind European trials in the 1980s and early 1990s; effects modest, inconsistent, and not replicated at registration-quality scale.

Schneider-Helmert reported partial normalization of polysomnographic sleep architecture and subjective sleep quality in chronic insomniac populations across an open and small-scale program in middle-aged and elderly patients [schneiderhelmert1984_insomnia, schneiderhelmert1986_efficacy, schneiderhelmert1987_24h]. The most methodologically rigorous trial, Bes et al. (1992) in Neuropsychobiology, a double-blind study in chronic insomniac patients, did not demonstrate convincing efficacy on polysomnographic endpoints [bes1992_insomnia]. Independent reviews characterize the chronic-insomnia evidence base as small, methodologically heterogeneous, and inconclusive [pollard2001_review, kovalzon2006_riddle].

Phase-shifted insomnia (circadian-disturbance insomnia) PRECLINICAL

Small German case-series report from 1987; not replicated.

Schneider-Helmert et al. (1987, Dtsch Med Wochenschr) reported a case-series of patients with phase-shifted insomnia who received DSIP, with reported reentrainment of sleep-wake schedule [schneiderhelmert1987_phaseshift]. The report is an uncontrolled case series and has not been replicated in any subsequent controlled trial identified in PubMed [kovalzon2006_riddle].

Narcolepsy PRECLINICAL

Open report only; benefit limited.

Schneider-Helmert (1984, Eur Neurol) reported the effects of DSIP in narcolepsy in a small uncontrolled series with limited and inconsistent benefit [schneiderhelmert1984_narcolepsy]. No subsequent controlled trial in narcolepsy has been identified [kovalzon2006_riddle].

Opioid withdrawal / opioid detoxification adjunct EMERGING

Small open trials in the 1980s and 1990s; results mixed; clinical development abandoned by the late 1990s.

Dick et al. (1984, Eur Neurol) reported subjective benefit from DSIP during alcohol and opiate withdrawal in an open European trial [dick1984_withdrawal]. Soyka and Rothenhaeusler (1997, Am J Psychiatry) and Backmund et al. (1998, J Clin Psychopharmacol) reported open-label clinical trials of DSIP in opioid detoxification with mixed results [soyka1997_opioid, backmund1998_opioid]. No double-blind randomized trial of DSIP for opioid withdrawal has been published, and clinical development effectively halted after 1998.

Alcohol withdrawal adjunct PRECLINICAL

Combined with opioid withdrawal in a single 1984 European report; no dedicated controlled trial.

Dick et al. (1984, Eur Neurol) reported DSIP use in withdrawal syndromes from alcohol and opiates in the same open series [dick1984_withdrawal]. No dedicated randomized controlled trial of DSIP for alcohol withdrawal has been identified in PubMed-indexed journals [kovalzon2006_riddle].

Chronic pain (analgesic adjunct) PRECLINICAL

Single pilot study from 1984; not replicated in controlled trials.

Larbig et al. (1984, Eur Neurol) reported a small clinical pilot study of DSIP in patients with chronic, pronounced pain episodes, with reported reductions in pain scores [larbig1984_pain]. The pilot was uncontrolled and has not been replicated [kovalzon2006_riddle].

Stress and stroke neuroprotection (preclinical) PRECLINICAL

Modern preclinical work in rodent models; no clinical translation.

Tukhovskaya et al. (2021, Molecules) reported recovery of motor function with DSIP after focal stroke in Sprague-Dawley rats [tukhovskaya2021_stroke]. Bobyntsev et al. (2016, Bull Exp Biol Med) reported DSIP effects on hepatocyte function during restraint stress [bobyntsev2016_hepatocyte]. These rodent findings have not advanced to human clinical trials.

Compounded DSIP, Delta Sleep-Inducing Peptide (503A)

Physicians may submit patient-specific prescription requests for pharmacy review. For DSIP, certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case and may depend on patient-specific documentation, ingredient status, source qualification, formulation feasibility, state requirements, and pharmacist judgment. The review starts with the evidence constraint: The evidence base for DSIP is old and

uneven. Early studies explored sleep architecture, stress response, opioid withdrawal, and neurologic symptoms, but the literature does not provide a modern, FDA-reviewed clinical dosing or safety program.

This ingredient is part of an evolving FDA review process. RonanRx is monitoring FDA's PCAC process and any subsequent agency action. FDA has scheduled emideltide, also referred to as DSIP, for discussion at the 23-24 Jul 2026 Pharmacy Compounding Advisory Committee meeting. Availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance. For DSIP, RonanRx ties that monitoring to the evidence limits described above and to any patient-specific documentation submitted by the prescriber.

Valid patient-specific prescription required. Supporting clinical rationale may be requested. Compounded medications are not FDA-approved. No consumer self-ordering, no office stock, no bulk dispensing. Requests for DSIP are reviewed before any preparation is made or released. A regulated request for DSIP starts with a clinician and an identified patient. It does not start with a consumer selecting a sleep peptide from a research-use-only marketplace.

DSIP, Delta Sleep-Inducing Peptide Formulations and Routes

Form	Concentration	Description
Lyophilized powder for reconstitution (research-peptide channel)	As marketed, typically 2, 5 mg vials reconstituted with bacteriostatic water; doses cited in marketing material are not derived from controlled studies	DSIP as sold in research-peptide channels is supplied as a lyophilized powder for reconstitution. Identity, potency, sterility, and endotoxin testing standards in those channels are heterogeneous and are not equivalent to USP <797> sterile-compounding standards. RonanRx does not source or dispense from these channels.

Routes used in published literature: subcutaneous, intravenous, intranasal.

DSIP, Delta Sleep-Inducing Peptide Dosing

Route	Population	Range	Duration	Study type
Intravenous	Adults with chronic insomnia (Schneider-Helmert series; small uncontrolled trials)	25, 50 nmol/kg intravenous bolus reported in the 1980s European clinical literature; no dose-response or pharmacokinetic study supports translation to current clinical use	—	Small uncontrolled European clinical series
Intravenous			—	

Route	Population	Range	Duration	Study type
	Chronic insomniac patients (Bes 1992 double-blind)	25 nmol/kg intravenous in a double-blind trial; the trial did not demonstrate convincing efficacy		Small double-blind RCT, N=16
Subcutaneous / intravenous	Opioid detoxification (Soyka 1997, Backmund 1998)	Doses reported in the original European trials; not validated for contemporary clinical practice	—	Open-label clinical trials

No contemporary, peer-reviewed dose-finding study of DSIP in humans has been published. The doses reported in the European clinical literature of the 1980s and 1990s are not derived from validated pharmacokinetic studies and have not been confirmed against modern outcome measures [bes1992_insomnia; soyka1997_opioid; backmund1998_opioid]. Reviews characterize the dose-response data as inconsistent across trials [pollard2001_review, kovalzon2006_riddle] [schneiderhelmert1987_24h].

Marketing-channel dose recommendations for DSIP from research-peptide vendors should not be treated as clinical guidance [schneiderhelmert1986_efficacy]. There is no FDA-labeled regimen, no USP monograph, and no validated patient-specific titration protocol.

DSIP, Delta Sleep-Inducing Peptide Safety

No contemporary controlled human safety dataset for DSIP has been published. The European clinical trials of the 1980s and 1990s reported broadly tolerable acute administration at the doses used, with no severe adverse events specifically attributed to DSIP, but these trials were small, short, and not designed to characterize a safety profile in the modern pharmacovigilance sense [11][20]. Reviews note the absence of any systematic adverse-event reporting framework for DSIP [21][22] [10].

FDA's broader concerns for research peptides under the interim 503A bulks framework, immunogenicity from peptide aggregation or impurities, manufacturing-related contaminant risk in non-cGMP supply chains, and absence of controlled human safety data, apply to DSIP by analogy [29] [17][19]. None of those concerns is addressed by a contemporary DSIP-specific study.

Patients who report self-use of DSIP from research-peptide channels should be assessed clinically for injection-site reactions, hypersensitivity, and any unexpected systemic events [10]. There is no validated assay panel for DSIP-specific monitoring.

Contraindications

Honest gap. No published contraindication framework for DSIP identified in PubMed-indexed journals or in FDA labeling. DSIP is not an FDA-approved drug and has no Prescribing Information.

Searched: PubMed, FDA Drug Compounding (bulks lists) on 2026-05-11 · terms *delta sleep-inducing peptide; DSIP contraindications; DSIP adverse*.

Drug interactions

Honest gap. No systematic drug-interaction characterization for DSIP identified in PubMed-indexed journals. The substance is not metabolized through a characterized CYP-mediated pathway because no validated human pharmacokinetic study has been published.

Searched: PubMed, DailyMed on 2026-05-11 · terms *DSIP drug interactions; delta sleep-inducing peptide interactions*.

Adverse events

Honest gap. No peer-reviewed published adverse-event series for DSIP identified beyond the small European trials of the 1980s and 1990s, which reported broadly tolerable acute administration without a systematic AE-monitoring framework. The FDA's interim 503A bulks framework treats research peptides such as DSIP as substances with significant safety risks pending controlled human data.

Searched: PubMed, FDA Adverse Event Reporting System (FAERS), limited public access on 2026-05-11 · terms *DSIP adverse events; delta sleep-inducing peptide adverse*.

Monitoring DSIP, Delta Sleep-Inducing Peptide Therapy

There is no validated monitoring framework for DSIP. No PubMed-indexed peer-reviewed publication has characterized the relevant safety laboratory or imaging follow-up for patients exposed to DSIP [kovalzon2006_riddle]. Clinicians evaluating patients who have self-administered DSIP from research-peptide channels should perform a clinical assessment focused on injection-site reactions, hypersensitivity manifestations, and any unexpected systemic signs, and document the exposure in the medical record.

DSIP, Delta Sleep-Inducing Peptide in Special Populations

DSIP, Delta Sleep-Inducing Peptide Evidence Quality

Evidence for DSIP is dominated by older European clinical literature from the 1980s and 1990s, small uncontrolled or single-center trials in chronic insomnia, narcolepsy, alcohol and opioid withdrawal, and chronic pain, together with a body of rodent and rabbit pharmacology from the same era [monnier1977_bbb; schneiderhelmert1984_insomnia; schneiderhelmert1984_narcolepsy]. The 1992 Bes et al [larbig1984_pain; soyka1997_opioid; backmund1998_opioid]. double-blind trial in chronic insomnia is the most methodologically rigorous study identified and did not demonstrate convincing efficacy on

polysomnographic endpoints [bes1992_insomnia] [graf1982_neurotransmitters; schneiderhelmert1986_efficacy].

Reviews in 2001 and 2006 characterize the DSIP corpus as inconclusive, no defined receptor, no validated pharmacokinetic model in humans, inconsistent clinical effects across small trials, and abandonment of clinical development by the late 1990s [pollard2001_review, kovalzon2006_riddle] [dick1984_withdrawal]. The 2006 Kovalzon and Strekalova review in J Neurochem explicitly titled DSIP 'a still unresolved riddle' after summarizing three decades of work [kovalzon2006_riddle] [schneiderhelmert1987_24h; schneiderhelmert1987_phaseshift].

Contemporary peer-reviewed activity is preclinical: rodent stroke and stress models [tukhovskaya2021_stroke, bobyntsev2016_hepatocyte], a BBB-transport review citing DSIP among historically studied peptides [banks2015_bbb_review], engineering work on fusion-peptide delivery constructs [zhang2017_fusion, mu2024_fusion], and a 2026 orthopaedic-peptides review situating DSIP among investigational peptides without an established clinical role [rahman2026_orthopaedic]. The evidence threshold remains uncertain for broad 503A use. RonanRx documents the substance so physician-submitted requests can be evaluated against the actual literature, FDA review status, and patient-specific rationale [fda_category2_bulks, fda503a] [schoenenberger1977_pnas].

Major DSIP, Delta Sleep-Inducing Peptide Clinical Studies

Study	Design	Participants	Duration	Finding
Schoenenberger and Monnier (1977, PNAS), Discovery and characterization	Bioassay-driven isolation of a delta-EEG-enhancing factor from cerebral venous blood of rabbits in electrically induced slow-wave sleep, transferred to recipient rabbits	—	—	Characterized a low-molecular-weight peptide that, when transferred, enhanced delta-band EEG activity in recipient rabbits, the founding observation that named the peptide [schoenenberger1977_pnas]
Schoenenberger et al. (1977, Pflugers Arch), Final isolation and characterization	Purification and structural characterization of the natural delta-EEG-	—	—	Reported final isolation, sequencing, and bioassay validation of the natural DSIP [schoenenberger1977_pflugers]

Study	Design	Participants	Duration	Finding
	enhancing nonapeptide			
Monnier et al. (1977, Experientia), Synthetic DSIP and BBB transport	Synthesis and bioassay of synthetic nonapeptide; radiolabel transport studies in rabbits	—	—	Synthetic DSIP reproduced bioactivity of the natural peptide and demonstrated transport across the blood-brain barrier [monnier1977_synthetic; monnier1977_bbb]
Scherschlicht et al. (1984, Eur Neurol), Pharmacological characterization	Narrative review of pharmacological effects of DSIP in animals	—	—	Summarized sleep, locomotor, and limited receptor-interaction findings in rodent and rabbit models from the Basel group and collaborators [scherschlicht1984_pharm]
Schneider-Helmert (1984, Eur Neurol), DSIP in insomnia	Open clinical series in adults with insomnia	—	—	Reported subjective and polysomnographic effects in a small uncontrolled series; effect sizes modest [schneiderhelmert1984_insomnia]
Schneider-Helmert (1984, Eur Neurol), DSIP in narcolepsy	Open clinical series in narcolepsy	—	—	Reported limited and inconsistent benefit [schneiderhelmert1984_narcolepsy]
Dick et al. (1984, Eur Neurol), Withdrawal syndromes	Open European clinical trial in alcohol and opiate withdrawal	—	—	Reported subjective benefit during withdrawal; uncontrolled and small [dick1984_withdrawal]
Larbig et al. (1984, Eur Neurol), Chronic pain pilot	Clinical pilot in patients with chronic, pronounced pain episodes	—	—	Reported reductions in pain measures; pilot, uncontrolled, not replicated [larbig1984_pain]
Schneider-Helmert (1986, Eur Neurol), Chronic insomniacs	Clinical efficacy report in middle-aged and elderly chronic insomniacs	—	—	Reported partial normalization of polysomnographic sleep parameters in older insomniacs [schneiderhelmert1986_efficacy]
		—	—	

Study	Design	Participants	Duration	Finding
Schneider-Helmert (1987, Eur Neurol), 24-hour sleep-wake	Clinical report on 24-hour sleep-wake behaviour in severe chronic insomnia			Reported effects on the 24-hour sleep-wake architecture; uncontrolled [schneiderhelmert1987_24h]
Bes et al. (1992, Neuropsychobiology), Double-blind chronic insomnia trial	Double-blind clinical trial of DSIP in chronic insomniac patients	16	—	Did not demonstrate convincing efficacy on polysomnographic endpoints, the most rigorous trial identified in the DSIP corpus [bes1992_insomnia]
Soyka and Rothenhaeusler (1997, Am J Psychiatry), DSIP in opioid detoxification	Short clinical report on use of DSIP in opioid detoxification	—	—	Reported mixed results; small open report [soyka1997_opioid]
Backmund et al. (1998, J Clin Psychopharmacol), Opioid detoxification open trial	Open clinical trial of DSIP for opioid detoxification	—	—	Mixed results; final clinical trial of DSIP identified before abandonment of the clinical program [backmund1998_opioid]
Pollard and Pomfrett (2001, Eur J Anaesthesiol), DSIP review	Narrative review	—	—	Emphasized absence of established mechanism and inconsistency of clinical effect [pollard2001_review]
Kovalzon and Strekalova (2006, J Neurochem), DSIP review	Narrative review titled 'Delta sleep-inducing peptide (DSIP): a still unresolved riddle'	—	—	Summarized three decades of inconclusive work, no defined receptor, no validated PK in humans, inconsistent clinical effects, abandonment of clinical development [kovalzon2006_riddle]
Tukhovskaya et al. (2021, Molecules), Focal stroke in rats	Preclinical rat focal stroke model	—	—	DSIP reportedly accelerated recovery of motor function after focal stroke [tukhovskaya2021_stroke]
Mu et al. (2024, Front Pharmacol), Fusion peptide in PCPA-induced insomnia mice	Preclinical mouse PCPA-induced insomnia model with Pichia-secreted fusion	—	—	Reported efficacy of an engineered DSIP-fusion peptide in a mouse insomnia model, preclinical, not translated to humans [mu2024_fusion]

Study	Design	Participants	Duration	Finding
	peptides incorporating DSIP			

DSIP, Delta Sleep-Inducing Peptide Pharmacokinetics & Pharmacodynamics

Pharmacokinetics

DSIP is a 9-amino-acid peptide with the sequence Trp-Ala-Gly-Gly-Asp-Ala-Ser-Gly-Glu. No validated human pharmacokinetic study has been published in PubMed-indexed journals [kovalzon2006_riddle]. In the original 1977 rabbit work, radiolabeled synthetic DSIP crossed the blood-brain barrier [monnier1977_bbb], and a 2015 review of BBB peptide transport cited DSIP among historically studied peptides [banks2015_bbb_review]. Half-life, distribution volume, clearance, and bioavailability in humans have not been validated; reviews emphasize the absence of a modern PK characterization [pollard2001_review, kovalzon2006_riddle].

As a small peptide, DSIP would be expected to clear by proteolytic catabolism rather than by CYP-mediated metabolism, but this has not been confirmed in controlled human studies.

Pharmacodynamics

Reported pharmacodynamic effects of DSIP in animal models include modulation of delta-band EEG activity, interactions with adrenergic and serotonergic neurotransmission, effects on pineal N-acetyltransferase, and small temperature effects [dick1984_withdrawal; larbig1984_pain; soyka1997_opioid; graf1982_neurotransmitters; tsunashima1994_temperature]. In humans, the small European clinical trials reported partial and inconsistent effects on polysomnographic sleep architecture, withdrawal symptom scores, and pain scores [schneiderhelmert1986_efficacy; schneiderhelmert1987_24h; bes1992_insomnia; schoenenberger1977_pnas; scherschlicht1984_pharm].

Reviews characterize the pharmacodynamic profile as heterogeneous and not anchored to a defined receptor or pathway [pollard2001_review, kovalzon2006_riddle] [backmund1998_opioid; graf1987_pineal_nat].

Comparing DSIP, Delta Sleep-Inducing Peptide Formulations

There is no FDA-approved formulation of DSIP. Comparison to a reference product is not possible because no reference product exists. Research-peptide-channel preparations vary in concentration, excipient profile, and reconstitution diluent; identity, potency, sterility, and endotoxin testing standards in those

channels are heterogeneous and are not equivalent to USP <797> sterile-compounding standards [usp_797].

Comparison to other sleep-related peptides studied in the same era (e.g., other neuropeptides assessed for sleep effects) is limited by the absence of head-to-head data and by the abandonment of the DSIP clinical program by the late 1990s [kovalzon2006_riddle] [usp_797].

DSIP, Delta Sleep-Inducing Peptide Storage and Handling

No validated stability data have been published for contemporary DSIP preparations. Research-peptide-channel product is typically supplied as lyophilized powder for reconstitution with bacteriostatic water and refrigerated storage after reconstitution, but these recommendations are not supported by peer-reviewed stability-indicating analytical data [kovalzon2006_riddle]. If RonanRx were ever to compound DSIP following Category 1 status, storage and beyond-use dating would be governed by USP <797> and by validated stability data developed at the pharmacy [usp_797].

DSIP, Delta Sleep-Inducing Peptide Compounding & Operations

503A compounding

Physicians may submit patient-specific prescription requests for pharmacy review. For DSIP, certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case and may depend on patient-specific documentation, ingredient status, source qualification, formulation feasibility, state requirements, and pharmacist judgment. The review starts with the evidence constraint: The evidence base for DSIP is old and uneven. Early studies explored sleep architecture, stress response, opioid withdrawal, and neurologic symptoms, but the literature does not provide a modern, FDA-reviewed clinical dosing or safety program.

This ingredient is part of an evolving FDA review process. RonanRx is monitoring FDA's PCAC process and any subsequent agency action. FDA has scheduled emideltide, also referred to as DSIP, for discussion at the 23-24 Jul 2026 Pharmacy Compounding Advisory Committee meeting. Availability may change after FDA review, PCAC discussion, final agency action, or state-board guidance. For DSIP, RonanRx ties that monitoring to the evidence limits described above and to any patient-specific documentation submitted by the prescriber.

Valid patient-specific prescription required. Supporting clinical rationale may be requested. Compounded medications are not FDA-approved. No consumer self-ordering, no office stock, no bulk dispensing. Requests for DSIP are reviewed before any preparation is made or released. A regulated request for DSIP starts with a clinician and an identified patient. It does not start with a consumer selecting a sleep peptide from a research-use-only marketplace.

Pharmacist review

For DSIP, the pharmacist review starts before any preparation is made. Valid patient-specific prescription required. Supporting clinical rationale may be requested. The pharmacist reviews ingredient status, sourcing, formulation feasibility, state requirements, patient-specific documentation, and whether dispensing is appropriate case by case.

Quality and traceability

If a DSIP preparation is approved after pharmacy review, RonanRx applies source documentation, formulation records, lot traceability, release checks, and storage controls appropriate to the actual dosage form. Research-use vial storage practices do not substitute for pharmacy-assigned storage, beyond-use dating, sterility controls when applicable, or recallable batch records.

Cold chain

If a DSIP preparation is approved after pharmacy review, RonanRx applies source documentation, formulation records, lot traceability, release checks, and storage controls appropriate to the actual dosage form. Research-use vial storage practices do not substitute for pharmacy-assigned storage, beyond-use dating, sterility controls when applicable, or recallable batch records.

Frequently Asked Questions About DSIP, Delta Sleep-Inducing Peptide

Can physicians request DSIP through RonanRx?

Physicians may submit patient-specific prescription requests for pharmacy review. Certain preparations may be available now when clinically appropriate, lawfully prescribed, and approved by the dispensing pharmacy. Availability is determined case by case. Compounded medications are not FDA-approved, and no consumer self-ordering, office stock, or bulk dispensing is offered.

What is DSIP?

DSIP, Delta Sleep-Inducing Peptide, is a 9-amino-acid peptide isolated in 1977 by Schoenenberger and Monnier from cerebral venous blood of rabbits placed in electrically induced slow-wave sleep [schoenenberger1977_pnas; schoenenberger1977_pflugers]. It was named for the increase in delta-band EEG activity seen in recipient rabbits after the dialysate was transferred.

Does DSIP actually induce sleep in humans?

The small European clinical trials of the 1980s and 1990s reported modest and inconsistent effects in chronic insomnia. The most methodologically rigorous trial, Bes et al. (1992), a double-blind study in chronic insomniac patients, did not demonstrate convincing efficacy on polysomnographic endpoints

[schneiderhelmert1986_efficacy; bes1992_insomnia; kovalzon2006_riddle]. A 2006 review in J Neurochem characterized DSIP as 'a still unresolved riddle.'

Is DSIP FDA-approved for anything?

No. DSIP has no FDA approval for any indication. There is no Prescribing Information, no USP monograph, and no FDA-approved manufactured product [fda_category2_bulks].

What about the European withdrawal and pain studies, don't those support DSIP?

Those reports are small, mostly uncontrolled, and from the 1980s and 1990s, Dick et al. (1984) in alcohol and opiate withdrawal, Larbig et al [dick1984_withdrawal]. (1984) in chronic pain, Soyka and Rothenhaeusler (1997) and Backmund et al [larbig1984_pain; backmund1998_opioid]. (1998) in opioid detoxification [soyka1997_opioid]. Effect sizes were modest or mixed, no replication in modern controlled trials has appeared, and clinical development was abandoned by the late 1990s [kovalzon2006_riddle].

Is the DSIP sold by research-peptide vendors safe?

Commercial DSIP is research-grade powder from non-pharmaceutical suppliers. Identity, potency, sterility, and endotoxin testing standards in those channels are heterogeneous and are not equivalent to USP <797> sterile-compounding standards. RonanRx does not source or dispense from these channels [fda_category2_bulks].

If a patient has already been using DSIP from a research-peptide source, what should they do?

Discuss the exposure with a treating clinician. There is no validated DSIP-specific monitoring panel, but a clinical assessment for injection-site reactions, hypersensitivity, and any unexpected systemic signs is appropriate, and the exposure should be documented in the medical record [kovalzon2006_riddle].

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How to Access DSIP, Delta Sleep-Inducing Peptide

Compounded DSIP, Delta Sleep-Inducing Peptide is dispensed under 503A on a patient-specific prescription. Depending on your role, the next step looks different.

FOR PRESCRIBING CLINICIANS

Offer this medication

A pharmacist will follow up within two business days. We'll cover state availability, supported formulations, and what integration looks like for your clinic.

ronanrx.com/request-partnership-call

PATIENT WITH A DOCTOR

Receive your prescription

If your doctor has prescribed DSIP, Delta Sleep-Inducing Peptide, sign up so we can prepare and ship your medication. The signup wizard collects intake and connects you to the prescribing workflow.

ronanrx.com/patients

PATIENT WITHOUT A DOCTOR

Find a partner clinic

RonanRx prescribes through partner clinics — we don't initiate prescriptions on this site. Read how the referral process works and how to find a partner clinic in your state.

ronanrx.com/find-clinic

Other compounds RonanRx makes

This monograph is one of many in the RonanRx formulary. Every compound below is prepared under 503A on a patient-specific prescription. Browse the full catalog at ronanrx.com/medications and ronanrx.com/peptides, or scan the codes at right for each index.

Medications

Peptides

MEDICATIONS (40)

Alpha-Lipoic Acid (ALA) — Antioxidant & mitochondrial
Coenzyme Q10 (CoQ10) — Antioxidant & mitochondrial
Glutathione — Antioxidant & mitochondrial
NAD+ / NMN — Antioxidant & mitochondrial
Compounded Topical Anesthetics (BLT, LET) — Dermatology
Topical Minoxidil — Dermatology
Topical Tretinoin — Dermatology
Compounded Magnesium — Energy & nutritional
Cyanocobalamin — Energy & nutritional
High-Dose Vitamin D — Energy & nutritional
Hydroxocobalamin — Energy & nutritional
Iron (Compounded) — Energy & nutritional
L-Carnitine — Energy & nutritional
Methylcobalamin (B12) — Energy & nutritional
Methylfolate — Energy & nutritional
Anastrozole — Hormone optimization
Clomiphene & Enclomiphene — Hormone optimization
DHEA — Hormone optimization
Estradiol — Hormone optimization
Estriol — Hormone optimization
Human Chorionic Gonadotropin (HCG) — Hormone optimization
Pregnenolone — Hormone optimization
Progesterone — Hormone optimization
Testosterone — Hormone optimization
Compounded Metformin — Metabolic & weight
Compounded Semaglutide — Metabolic & weight
Compounded Tirzepatide — Metabolic & weight
Lipotropic Injection (MIC, MICC) — Metabolic & weight
Low-Dose Naltrexone (LDN) — Metabolic & weight
Naltrexone-Bupropion Combination — Metabolic & weight
Topiramate — Metabolic & weight
Bremelanotide / PT-141 — Sexual health
Compounded Sildenafil — Sexual health
Compounded Tadalafil — Sexual health
Trimix Injection — Sexual health
Compounded Gabapentin — Sleep & recovery
Compounded Melatonin — Sleep & recovery
Compounded T3 (Liothyronine) — Thyroid
Compounded T3/T4 Combinations — Thyroid
Compounded T4 (Levothyroxine) — Thyroid

PEPTIDES (21)

Sermorelin — Available now

Tesamorelin — Available now

AOD-9604 — Growth-hormone axis (under FDA review)

CJC-1295 — Growth-hormone axis (under FDA review)

GHRP-2 / GHRP-6 — Growth-hormone axis (under FDA review)

Hexarelin — Growth-hormone axis (under FDA review)

Ipamorelin — Growth-hormone axis (under FDA review)

MK-677 / Ibutamoren — Growth-hormone axis (under FDA review)

5-Amino 1MQ — Metabolic & longevity (under FDA review)

Epitalon / Epithalon — Metabolic & longevity (under FDA review)

MOTS-C — Metabolic & longevity (under FDA review)

Thymosin Alpha-1 / Thymalin — Metabolic & longevity (under FDA review)

DSIP, Delta Sleep-Inducing Peptide — Neuro & cognitive (under FDA review)

Selank — Neuro & cognitive (under FDA review)

Semax — Neuro & cognitive (under FDA review)

Vasoactive Intestinal Peptide (VIP) — Neuro & cognitive (under FDA review)

BPC-157 — Tissue repair (under FDA review)

KPV — Tissue repair (under FDA review)

LL-37 — Tissue repair (under FDA review)

Pentadeca Arginate (PDA) — Tissue repair (under FDA review)

TB-500 / Thymosin Beta-4 — Tissue repair (under FDA review)