Summary Report

Nandrolone decanoate

Prepared for:

Food and Drug Administration
Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks List
Grant number: 5U01FD005946

Prepared by:

University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI)
University of Maryland School of Pharmacy

December 2020

This report was supported by the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services (HHS) as part of a financial assistance award (U01FD005946) totaling $2,342,364, with 100 percent funded by the FDA/HHS. The contents are those of the authors and do not necessarily represent the official views of, nor an endorsement by, the FDA/HHS or the U.S. Government.

Table of Contents

Table of Tables

Frequently Used Abbreviations

AIDS	Acquired immune deficiency syndrome
API	Active Pharmaceutical Ingredient
CKD	Chronic kidney disease
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration
HIV	Human immunodeficiency virus
IRB	Institutional Review Board
LMB	Lean body mass
OTC	Over-the-counter
ROA	Route of administration
SME	Subject matter expert
UK	United Kingdom
US	United States

INTRODUCTION

This report was created to assist the Food and Drug Administration (FDA) in their evaluation of the use of nandrolone decanoate (UNII code: H45187T098), which was nominated for use as a bulk drug substance in compounding by outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act.

The aim of this report was to describe how nandrolone decanoate is used in clinical research and practice to diagnose, prevent, or treat disease. Due to the broad, exploratory nature of this aim, scoping review methodology was used. Following the scoping review framework, a systematic literature review was conducted and healthcare practitioners were consulted to identify how nandrolone decanoate has been used historically and currently.[1-3] Assessment of study quality and risk of bias were not performed because the aim of this report was not to make specific recommendations on the use of this substance in clinical practice.[1,4,5] Rather, the aim was to summarize the available evidence on the use of nandrolone decanoate and thereby assist the FDA to determine whether there is a need for the inclusion of this substance on the 503B Bulks List.

REVIEW OF NOMINATIONS

Nandrolone decanoate was nominated for inclusion on the 503B Bulks List by AnazaoHealth Corporation, Olympia Compounding Pharmacy, the Outsourcing Facilities Association (OFA), and David Smith.

Nandrolone decanoate was nominated for anemia, chronic kidney disease (CKD), osteoporosis, male hypogonadism, acquired immune deficiency syndrome (AIDS)-associated wasting syndrome (cachexia) and other wasting syndromes via a 200 mg/mL intramuscular injection.

Nominators provided references from published peer-reviewed literature to describe the pharmacology and support the clinical use of nandrolone decanoate.[6-11]

Reasons provided for nomination to 503B Bulks List include:

- There are no products containing nandrolone decanoate currently on the market; Deca-Durabolin® (nandrolone decanoate) was discontinued by the manufacturer.
- Compounded product may be the only product to effectively treat the indication for which it is intended.
- Patient need for dosage form or strength that is not available commercially.
- Patient sensitivities to dyes, fillers, preservatives or other excipients in manufactured products.
- Manufacturer backorder.
- Possible patient sensitivities to manufactured product dyes, fillers, preservatives, and other excipients.
- The need for accuracy is another reason to use the bulk drug substance instead of the finished product. The finished product may potentially introduce unacceptable inaccuracies into compounded medications and may have variance in the actual API, often with a 5-15% deviation from the labeled strength/potency.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of nandrolone decanoate products in the United States (US) and around the world. The World Health

Organization, the European Medicines Agency (EMA), and globalEDGE were used to identify regulatory agencies in non-US countries. The medicine registers of non-US regulatory agencies were selected for inclusion if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information, specifically, product trade name, active ingredient, strength, form, route of administration (ROA), and approval status, provided in a useable format. Based on these criteria, the medicine registers of 13 countries/regions were searched: US, Canada, European Union (EU), United Kingdom (UK), Ireland, Belgium, Latvia, Australia, New Zealand, Saudi Arabia, Abu Dhabi, Hong Kong, and Namibia. Both the EMA and the national registers of select EU countries (Ireland, UK, Belgium, and Latvia) were searched because some medicines were authorized for use in the EU and not available in a member country and vice versa.

Each medicine register was searched for nandrolone decanoate; name variations of nandrolone decanoate were entered if the initial search retrieved no results. The following information from the search results of each register was recorded in a spreadsheet: product trade name; active ingredient; strength; form; ROA; status and/or schedule; approval date. Information was recorded only for products with strengths, forms, and/or ROA similar to those requested in the nominations.

In addition to the aforementioned medicine registers, the DrugBank database (version 5.1.5) and the Natural Medicines database were searched for availability of over-the-counter (OTC) products containing nandrolone decanoate. The availability of OTC products (yes/no) in the US and the ROA of these products were recorded in a spreadsheet. Individual product information was not recorded.

Systematic literature review

Nandrolone decanoate is a component of an FDA-approved product that has been discontinued by the manufacturer, not for safety or efficacy reasons. The desired compounded products identified in the submitted nominations do not substantially differ from the commercially available product. Therefore, a systematic literature review was not conducted.

Interviews

Semi-structured interviews with subject matter experts (SMEs) were conducted to understand how and in what circumstances nandrolone decanoate was used in a clinical setting. The systematic literature review and indications from the nominations were reviewed to identify the following medical specialties that would potentially use nandrolone decanoate: endocrinology, hematology, infectious disease, naturopathy, nephrology, oncology, osteopathic medicine, primary care and internal medicine, rheumatology, and urology. Potential SMEs within the relevant medical specialties were identified through recommendations and referrals from professional associations, colleagues' professional networks, and authors of relevant literature. In addition, the American Society of Health-System Pharmacists (ASHP) and select outsourcing facilities were contacted for interviews and referrals to additional SMEs. SMEs provided oral informed consent to be interviewed and audio recorded. Interviews lasting up to 60 minutes were conducted via telephone, audio recorded, and professionally transcribed. The transcriptions and notes were entered into NVivo 12 (QSR International) for qualitative data analysis. Several members of the research team independently coded the transcriptions of two representative interviews for themes. The team members discussed the codes that emerged from their independent analysis, as well as those codes that were determined a priori. The code book was developed out of the integration of these coding schemes.

Survey

A survey was distributed to the members of professional medical associations to determine the use of nandrolone decanoate in clinical practice. The online survey was created using Qualtrics® software (refer to Appendix 2 for complete survey). A Google™ search was conducted to identify the professional associations in the US for the relevant medical specialties. An association's website was searched to identify the email of the executive director, regulatory director, media director, association president, board members, or other key leaders within the organization to discuss survey participation. If no contact information was available, the "contact us" tab on the association website was used. An email describing the project and requesting distribution of the survey to the association's members was sent to the identified person(s). Associations that declined, did not respond, or did not provide significant data in project Year 1 were not contacted to distribute the project Year 2 surveys.

The survey was posted on the project website and the survey link was distributed to the associations that agreed to participate (refer to Appendix 3 for associations that participated and those that did not).

Participation was anonymous and voluntary. The estimated time for completion was 15 minutes with a target of 50 responses per survey.

The University of Maryland, Baltimore Institutional Review Board (IRB) and the FDA IRB reviewed the interview and survey methods and found both to be exempt. The Office of Management and Budget approved this project.

CURRENT AND HISTORIC USE

Results of background information

- Nandrolone decanoate is not available as an FDA-approved product in the nominated dosage form and ROA.
- Nandrolone decanoate was available as an FDA-approved 25-200 mg/mL injection that was discontinued, not for safety or efficacy reasons.
- Nandrolone decanoate is not available as an OTC product in the US.
- There is a current United States Pharmacopeia (USP) monograph for nandrolone decanoate.
- Nandrolone decanoate is available in the nominated dosage form and ROA in Abu Dhabi, Australia, Belgium, Hong Kong, Latvia, New Zealand, and UK.

Table 1. Currently approved products – US

No approved products in the US

Table 2. Currently approved products – select non-US countries and regions[a]

Active Ingredient[b]	Concentration	Dosage Form	Route of Administration	Approved for Use		
				Country	Status	Approval Date
Nandrolone decanoate	25, 50 mg/mL	Solution	Intramuscular injection	Abu Dhabi	Active	–
				Australia	Prescription	2/22/2007
				Belgium		5/31/1961
				Hong Kong		6/8/1979
				Latvia		5/7/1997
				New Zealand		12/31/1969
				UK		9/27/1988

Abbreviation: "– ", not mentioned.

[a]Medicine registers of national regulatory agencies were searched if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information (product trade name, active ingredient, strength, form, ROA, and approval status) provided in a useable format. Information was recorded only for products with strengths, forms, and/or ROA similar to those requested in the nominations. See Methodology for full explanation.

[b]Nandrolone decanoate used as the standard for name variations, including nandroloni decanoas.

Results of literature review

No literature review was conducted.

Pharmacology and historical use

Seventeen studies were identified that provided valuable information about the pharmacology and historical use of nandrolone decanoate.

Nandrolone decanoate is an anabolic steroid that is typically administered as a weekly intramuscular injection and has been studied for use in a variety of clinical indications including orphan drug designations for Duchenne and Becker muscular dystrophy and limb-girdle muscular dystrophy.[12] Nandrolone decanoate has been discontinued by Watson Pharmaceuticals since March 20, 2007 due to the unavailability of the active pharmaceutical ingredient.[13]

Muscle wasting and weakness can be seen in hemodialysis and human immunodeficiency virus (HIV)-infected patients. There was a noted increase in hemoglobin and hematocrit when anabolic steroids, like nandrolone decanoate, were used for anemia of CKD and nandrolone decanoate has been shown to increase body mass and strength.[8,15] In a randomized controlled trial done by Johansen et al., hemodialysis patients received nandrolone decanoate or placebo administered weekly via an intramuscular injection (100 mg for women; 200 mg for men) combined with lower extremity resistance exercise 3 times a week for 12 weeks during hemodialysis sessions.[8] Patients on nandrolone decanoate had a statistically significant average increase in lean body mass and decrease of fat mass.[8] The authors concluded that both nandrolone and resistance exercise "produced anabolic effects among patients who were on hemodialysis," and that "further studies are needed to determine whether these interventions improve survival."[8]

For HIV patients, there have been several studies done comparing nandrolone to placebo, another comparator, or in combination with resistance exercise. In general, the studies have reported that nandrolone has increased body weight. Sattler et al.[10] gave weekly nandrolone injections (Deca-Durabolin®) alone for 16 weeks, or in combination with resistance exercise. Total body weight gain, lean body mass, muscle size, and strength improvement in the nandrolone group were statistically significant, with increases in lean body mass and muscular strength even more pronounced in the combined nandrolone and exercise group.[10] Mulligan et al.[9] conducted a randomized controlled trial in which HIV-infected women received nandrolone decanoate 100 mg or placebo every other week by intramuscular injection. They concluded that nandrolone could be "generally safe and beneficial in reversing weight loss and lean tissue loss in women with HIV infection and other chronic catabolic diseases."[9] Gold et al. compared nandrolone decanoate 150 mg with placebo or testosterone 250 mg intramuscularly every 2 weeks for 12 weeks in patients with HIV-associated wasting syndrome and concluded that the nandrolone group had an increased body weight and fat-free mass compared to that of the placebo and testosterone groups.[6] Another Gold study used nandrolone decanoate alone as an 100 mg/mL intramuscular injection every 2 weeks for 16 weeks and also reported "beneficial effects on weight, LBM [lean body mass], and quality of life" in patients with mild-moderate HIV wasting.[7]

Nandrolone decanoate could also be used for anemia of CKD because it can "increase serum erythropoietin levels, packed cell volume, red cell mass, and hemoglobin concentration."[15] A 2012 meta-analysis of randomized controlled trials comparing nandrolone to erythropoietin for anemia of chronic kidney disease found that there was no difference between nandrolone and erythropoietin for treatment of anemia of CKD in men over 50 years old.[16] Nandrolone was used in all trials reported in the meta-analysis at a dose of 100-200 mg/week intramuscularly for 3 or 6 months.[16] The authors

concluded that nandrolone could be used as a cheaper alternative to erythropoietin in resource-limited countries.[16] A 2014 Cochrane review included 8 studies that used nandrolone decanoate as an intramuscular injection, some in combination with erythropoietin or as the comparator. The review concluded that, due to limited evidence and the quality of the studies, there was no compelling evidence to indicate whether nandrolone decanoate "increased hemoglobin or prealbumin, or decreased blood urea nitrogen (BUN), serum creatinine (SCr), aspartate aminotransferase (AST), alanine aminotransferase (ALT), cholesterol, triglycerides (TG), high-density lipoproteins (HDL), adverse events, or low-density lipoproteins (LDL)."[18]

Nandrolone has also been studied either alone or in combination during the rehabilitation period for fractures because osteoporotic fractures can be related "to decreased anabolic stimuli associated with the aging process."[18] A 2014 Cochrane review included 3 trials that looked at the use of nandrolone injection in hip fracture surgery recovery in females 65 years or older.[20] One included study used nandrolone 25 mg intramuscularly every third week for one year in combination with vitamin D3 and calcium compared to calcium alone as the control group,[20] while another combined nandrolone (25 mg every three weeks) with a protein-rich formula in addition to daily calcium and vitamin D compared to 2 control groups with nandrolone.[22] The last included study compared nandrolone 2 mg/kg weekly intramuscular injections alone to placebo.[23] With a high risk of bias associated with the included studies due to methodological shortcomings and the imprecision of results, the review concluded that there was not enough available evidence to draw conclusions for the "functional outcome and adverse events of anabolic steroids, either separately or in combination with nutritional supplements, after surgical treatment of hip fracture in older people."[20]

For male hypogonadism, nandrolone is considered as a possibility due to a "weak affinity for the androgen receptor after 5α-reductase reduction."[11] Decreases in androgen levels correlate with muscle mass loss, so there is a potential that gains in muscle mass could help with treating male hypogonadism.[11] There need to be studies to investigate if exercise with nandrolone could help with male hypogonadism via improvements with both muscle mass and strength to result in "long-term elevations of native testosterone levels."[11]

Table 3. Types of studies

No literature review was conducted.

Table 4. Number of studies by country

No literature review was conducted.

Table 5. Summary of included studies

No literature review was conducted.

Table 6. Dosage by indication – US

No literature review was conducted.

Table 7. Dosage by indication – non-US countries

No literature review was conducted.

Table 8. Number of studies by combination

No literature review was conducted.

Table 9. Compounded products – US

No literature review was conducted.

Table 10. Compounded products – non-US countries

No literature review was conducted.

Results of interviews

Two hundred eighty-five SMEs were contacted for interviews; 96 agreed to be interviewed, and 189 declined or failed to respond to the interview request. Eight SMEs discussed nandrolone decanoate. Amongst these 8 SMEs, there were 5 medical doctors, 1 pharmacist, 1 nurse practitioner, and 1 regulatory specialist. The SMEs specialized and/or were board-certified in HIV medicine, infectious disease, internal medicine, oncology/hematology, rheumatology, sexual/reproductive health, and urology, working in academia, academic medical centers, pharmacy/pharma companies, and private practice/clinics. The SMEs had been in practice for 9 to 22 years.

Almost all the SMEs had never used or were not familiar with nandrolone. One SME specializing in oncology expressed having never used nandrolone but would like to look into nandrolone for wasting syndromes because it is an issue in leukemia patients. Another oncology SME stated that something for wasting syndromes in cancer would be beneficial because there are not a lot of options. Many of their patients are using medical cannabis which the practitioner cannot order and Marinol® (dronabinol) is ineffective. This SME preferred a medication that they could order. Nandrolone, as an anabolic steroid, does make sense because "steroids make you hungry and energetic." However, there could be potential concerns with steroids affecting the patient's immune system while they are on immunotherapy, increasing glucose levels in diabetics, as well as long-term side effects like weakness in the legs and the inability to walk.

A 503A pharmacy stated they have compounded nandrolone and commented that "there is definitely a niche but [they] do not think it is huge." Additionally, one SME specializing in urology uses compounded nandrolone from Empower Pharmacy for male hypogonadism. This SME stated that nandrolone is fantastic for patients with hypogonadism who have joint pain such as rotator cuff pain. There have been animal studies that have consistently shown the benefits of nandrolone in joint pain. This SME also uses nandrolone in patients who respond poorly to testosterone therapy to help improve the patient's response to testosterone and to get better relief for their hypogonadal symptoms.

Nandrolone is very good for building muscle mass (bodybuilders use nandrolone) because it is a very powerful biogenic agent. One SME noted that "All these testosterones have a ratio between biogenic, which is muscle-building, and androgenic, which is more hair-producing, male testosterone producing."

Nandrolone is about a 10:1 biogenic to androgenic, which can be beneficial in patients who are on testosterone and struggling to change their body type (less chubby and more muscular). If a patient is working out but not seeing results, then one SME stated that patients can be given a little nandrolone to potentially decrease the amount of time a patient needs to be on testosterone. This SME stated that nandrolone is usually not used initially.

Results of survey

Zero people responded to the survey distributed via professional medical associations and available on the project website.

Table 11. Characteristics of survey respondents

No respondents to survey distributed via professional medical associations

Table 12. Conditions for which nandrolone decanoate prescribed or administered

No respondents to survey distributed via professional medical associations

Table 13. Reasons for using compounded nandrolone decanoate

No respondents to survey distributed via professional medical associations

Table 14. Use of non-patient-specific compounded nandrolone decanoate

No respondents to survey distributed via professional medical associations

CONCLUSION

Nandrolone decanoate was nominated for inclusion on the 503B Bulks List for anemia, CKD, osteoporosis, male hypogonadism, AIDS-associated wasting syndrome (cachexia) and other wasting syndromes via a 200 mg/mL intramuscular injection. Nandrolone decanoate was available as an FDA-approved 25-200 mg/mL injection that was discontinued, not for safety or efficacy reasons. It is available in the nominated dosage form and ROA in Abu Dhabi, Australia, Belgium, Hong Kong, Latvia, New Zealand, and UK.

No literature review was conducted but from the studies identified for background information, nandrolone is an anabolic steroid administered as an injection. Indications mentioned for nandrolone include Duchenne and Becker muscular dystrophy and limb-girdle muscular dystrophy (orphan drug designations), muscle wasting and weakness in hemodialysis and HIV-infected patients, anemia of CKD, osteoporotic fractures, and male hypogonadism.

Almost all the SMEs had never used or were not familiar with nandrolone, except one SME who used compounded nandrolone for male hypogonadism and a 503A pharmacy who stated they have compounded nandrolone. That SME said nandrolone is fantastic for patients with hypogonadism who have joint pain, need to improve muscle mass gains to stop testosterone faster, and patients who respond poorly to testosterone therapy. Both SMEs specializing in oncology mentioned that something for wasting syndromes in cancer would be beneficial.

Zero people responded to the survey distributed via professional medical associations and available on the project website.

REFERENCES

1. Arksey H, O'Malley L. Scoping studies: Towards a methodological framework. *International Journal of Social Research Methodology: Theory and Practice.* 2005;8(1):19-32.
2. Colquhoun HL, Levac D, O'Brien KK, et al. Scoping reviews: time for clarity in definition, methods, and reporting. *J Clin Epidemiol.* 2014;67(12):1291-1294.
3. Levac D, Colquhoun H, O'Brien KK. Scoping studies: Advancing the methodology. *Implementation Science.* 2010;5(1).
4. Peters MDJ, Godfrey CM, Khalil H, McInerney P, Parker D, Soares CB. Guidance for conducting systematic scoping reviews. *International Journal of Evidence-Based Healthcare.* 2015;13(3):141-146.
5. Munn Z, Peters MDJ, Stern C, Tufanaru C, McArthur A, Aromataris E. Systematic review or scoping review? Guidance for authors when choosing between a systematic or scoping review approach. *BMC Med Res Methodol.* 2018;18(1):143-143.
6. Gold J, Batterham MJ, Rekers H, et al. Effects of nandrolone decanoate compared with placebo or testosterone on HIV-associated wasting. *HIV Med.* 2006;7(3):146-155.
7. Gold J, High HA, Li Y, et al. Safety and efficacy of nandrolone decanoate for treatment of wasting in patients with HIV infection. *AIDS.* 1996;10(7):745-752.
8. Johansen KL, Painter PL, Sakkas GK, Gordon P, Doyle J, Shubert T. Effects of resistance exercise training and nandrolone decanoate on body composition and muscle function among patients who receive hemodialysis: A randomized, controlled trial. *J Am Soc Nephrol.* 2006;17(8):2307-2314.
9. Mulligan K, Zackin R, Clark RA, et al. Effect of nandrolone decanoate therapy on weight and lean body mass in HIV-infected women with weight loss: a randomized, double-blind, placebo-controlled, multicenter trial. *Archives of internal medicine.* 2005;165(5):578-585.
10. Sattler FR, Jaque SV, Schroeder ET, et al. Effects of pharmacological doses of nandrolone decanoate and progressive resistance training in immunodeficient patients infected with human immunodeficiency virus. *J Clin Endocrinol Metab.* 1999;84(4):1268-1276.
11. Wu C, Kovac JR. Novel uses for the anabolic androgenic steroids nandrolone and oxandrolone in the management of male health. *Curr Urol Rep.* 2016;17(10):72-72.
12. U.S. Food and Drug Administration. Orphan Drug Designations and Approvals. U.S. Food and Drug Administration,. https://www.accessdata.fda.gov/scripts/opdlisting/oopd/. Accessed July 1, 2020.
13. Nandrolone decanoate. IBM Micromedex. IBM Watson Health Web site. https://www.micromedexsolutions.com. Accessed July 1, 2020.
14. Balog DL, Epstein ME, Amodio-Groton MI. HIV wasting syndrome: treatment update. *Annals of Pharmacotherapy.* 1998;32(4):446-458.
15. Aggarwal H, Sehgal R, Singh S, Nand N, Bharti K, Chakrabarti D. Evaluation of efficacy of low dose recombinant human erythropoietin in combination with androgen therapy in anaemia of chronic renal failure. *Journal, Indian Academy of Clinical Medicine.* 2005;6(3):208-215.
16. Adamu B, Ma'aji SM, Erwin PJ, Tleyjeh IM. Meta-analysis of randomized controlled trials on androgens versus erythropoietin for anaemia of chronic kidney disease: Implications for developing countries. *International Journal of Nephrology.* 2012;2012:580437.

17. Yang Q, Abudou M, Xie XS, Wu T. Androgens for the anaemia of chronic kidney disease in adults. *Cochrane Database of Systematic Reviews.* 2014(10):CD006881.

18. Cederholm T, Hedstrom M. Nutritional treatment of bone fracture. *Current Opinion in Clinical Nutrition & Metabolic Care.* 2005;8(4):377-381.

19. Farooqi V, van den Berg ME, Cameron ID, Crotty M. Anabolic steroids for rehabilitation after hip fracture in older people. *Cochrane Database of Systematic Reviews.* 2014(10):CD008887.

20. Hedström M, Sjöberg K, Brosjö E, Aström K, Sjöberg H, Dalén N. Positive effects of anabolic steroids, vitamin D and calcium on muscle mass, bone mineral density and clinical function after a hip fracture. A randomised study of 63 women. *J Bone Joint Surg Br.* 2002;84(4):497-503.

21. Tidermark J, Ponzer S, Carlsson P, et al. Effects of protein-rich supplementation and nandrolone in lean elderly women with femoral neck fractures. *Clin Nutr.* 2004;23(4):587-596.

22. Sloan JP, Wing P, Dian L, Meneilly GS. A pilot study of anabolic steroids in elderly patients with hip fractures. *J Am Geriatr Soc.* 1992;40(11):1105-1111.

APPENDICES

Appendix 1. Search strategies for bibliographic databases

No literature review was conducted.

Appendix 2. Survey instrument for professional medical associations

Welcome. We want to understand your clinical use of compounded nandrolone decanoate. Your feedback will help the Food and Drug Administration (FDA) develop a list of drugs that can be used in compounding by 503B outsourcing facilities. Your anonymous responses will be shared with the FDA. The time required to complete this survey is approximately 10-15 minutes.

If you have additional questions or concerns about this study, please email: compounding@rx.umaryland.edu.

If you have questions about your rights as a research subject, please contact HRPO at 410-760-5037 or hrpo@umaryland.edu.

Thank you,

Dr. Ashlee Mattingly,
Principal Investigator
The University of Maryland School of Pharmacy

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

OMB Control No. 0910-0871
Expiration date: June 30, 2022

1. How familiar are you with the following terms?

	Very familiar	Somewhat familiar	Not familiar
Compounded drugs (medications prepared to meet a patient-specific need)	o	o	o
503A Compounding pharmacy (a pharmacy that prepares compounded medications prescribed by practitioners to meet a patient-specific need)	o	o	o
503B Outsourcing facility (a facility that compounds larger quantities without the receipt of a patient-specific prescription)	o	o	o

2. Do you prescribe or administer nandrolone decanoate to your patients?
   - o Yes
   - o No
3. I prescribe or administer nandrolone decanoate for the following conditions or diseases: (check all that apply)
   - o Acquired immune deficiency syndrome (AIDS) – associated wasting syndrome (cachexia)
   - o Anemia
   - o Chronic renal failure
   - o Male hypogonadism
   - o Osteoporosis
   - o Other (please describe) _____
4. I use nandrolone decanoate with my patients as the following: (check all that apply)
   - o FDA-approved drug product
   - o Compounded drug product
   - o Over-the-counter drug product
   - o Dietary supplement (e.g. vitamin or herbal supplement sold in retail)
   - o Other (please describe)

5. I use compounded nandrolone decanoate because: (check all that apply)
    - o Commercial products are not available in the dosage form, strength, or combination I need. (please explain) _____
    - o Patient allergies prevent me from using commercially available products. (please explain) _____
    - o Patient conditions prevent me from using commercially available products. (please explain) _____
    - o There are no commercially available products containing nandrolone decanoate.
    - o Other (please explain) _____

6. Do you stock non-patient-specific compounded nandrolone decanoate at your practice?
    - o Yes
    - o No
    - o I'm not sure

7. I obtain compounded nandrolone decanoate from the following: (check all that apply)
    - o Compound myself at my practice
    - o Have the product compounded by an in-house pharmacy
    - o Purchase, or have a patient purchase, from a compounding pharmacy
    - o Purchase, or have a patient purchase, from an outsourcing facility
    - o Other (please explain) _____

8. What is your practice setting? (check all that apply)
    - o Physician office/private practice
    - o Outpatient clinic
    - o Hospital/health system
    - o Academic medical center
    - o Emergency room
    - o Operating room
    - o Other (please describe) _____

9. What degree do you hold? (check all that apply)
    - o Doctor of Medicine (MD)
    - o Doctor of Osteopathic Medicine (DO)
    - o Doctor of Medicine in Dentistry (DMD/DDS)
    - o Doctor of Pharmacy (PharmD) or Bachelor of Science in Pharmacy (BS Pharm)
    - o Naturopathic Doctor (ND)
    - o Nurse Practitioner (NP)
    - o Physician Assistant (PA)
    - o Other (please describe)

Appendix 3. Survey distribution to professional associations

Specialty	Association[a]	Agreed/Declined, Reason for Declining
Allergy/Immunology	American Academy of Allergy, Asthma, and Immunology (AAAI)	Declined – survey not approved
Anesthesia	American Society of Regional Anesthesia and Pain Medicine (ASRA)	Declined – failed to respond
	Society for Ambulatory Anesthesia (SAMBA)	Declined – failed to respond
	Society for Neuroscience in Anesthesiology and Critical Care	Declined – failed to respond
Critical Care	Critical Care Societies Collaborative	Declined – failed to respond
Dentistry & Oral Medicine	Academy of General Dentistry (AGD)	Declined – provided interview referrals
	American Dental Association (ADA)	Declined – failed to respond
Dermatology	American Academy of Dermatology (AAD)	Agreed
	American Osteopathic College of Dermatology (AOCD)	Declined – not interested
Endocrinology	The Endocrine Society (ENDO)	Agreed
	Pediatric Endocrine Society	Agreed
Gastroenterology	American Gastroenterological Association (AGA)	Declined – failed to respond
	Obesity Medicine Association (OMA)	Declined – did not have anyone to contribute to research
Hematology	American Society of Hematology (ASH)	Declined – does not distribute surveys
Infectious Disease	American Academy of HIV Medicine (AAHIVM)	Declined – failed to respond
Medicine	American Medical Association (AMA)	Declined – failed to respond

Naturopathy	American Association of Naturopathic Physicians (AANP)	Agreed
	The Oncology Association of Naturopathic Physicians (OncANP)	Agreed
Nephrology	American College of Clinical Pharmacists: Nephrology Practice Network	Agreed
	American Society of Nephrology	Declined – provided interview referrals
Nutrition	American Society for Parenteral and Enteral Nutrition (ASPEN)	Declined – provided interview referrals
Obstetrics and Gynecology	American Gynecological and Obstetrical Society (AGOS)	Declined – failed to respond
	Nurse Practitioners in Women's Health	Agreed
Ophthalmology	American Academy of Ophthalmology (AAO)	Agreed
Otolaryngology	American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS)	Declined – survey not approved
Pain Management	American Academy of Pain Medicine (AAPM)	Declined – survey not approved
	American Academy of Physical Medicine and Rehabilitation	Declined – failed to respond
Pediatrics and Neonatology	American Academy of Pediatrics (AAP)	Agreed
Primary Care	American College of Physicians (ACP)	Declined – failed to respond
Psychiatry	American Academy of Clinical Psychiatrists	Declined – failed to respond
	American Association for Geriatric Psychiatry	Declined – failed to respond
Rheumatology	American College of Rheumatology (ACR)	Agreed

Surgery	Ambulatory Surgery Center Association (ASCA)	Agreed
	American Academy of Orthopaedic Surgeons (AAOS)	Declined – no interest in participation from members
	American Association of Hip and Knee Surgeons (AAHKS)	Declined – only send surveys from members
	American College of Surgeons (ACS)	Agreed
	American Society for Metabolic and Bariatric Surgery (AMBS)	Declined – only send surveys from members
	The Association of Bone and Joint Surgeons	Declined – failed to respond
	Physician Assistants in Orthopaedic Surgery	Declined – failed to respond
	Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)	Declined – failed to respond
	Society of Gynecologic Surgeons (SGS)	Declined – policy limits number of surveys per year and do not have a method to identify if any of the SGS members are using ipamorelin
Toxicology	American Academy of Environmental Medicine (AAEM)	Declined – failed to respond
Urology	Sexual Medicine Society of North America (SMSNA)	Agreed

[a]Associations that declined in Year 1 were not contacted in Year 2.