

**New York State Department of Taxation and Finance**  
**Office of Counsel**  
**Advisory Opinion Unit**

TSB-A-10(9)S  
Sales Tax  
March 8, 2010

STATE OF NEW YORK  
COMMISSIONER OF TAXATION AND FINANCE

ADVISORY OPINION

PETITION NO. S091207A

On December 7, 2009, the Department of Taxation and Finance received a Petition for Advisory Opinion from [REDACTED]. Petitioner asks whether Mirena, a product it sells to healthcare providers, is subject to sales tax. Mirena is a drug for purposes of Tax Law section 1115(a)(3). Therefore, petitioner's receipts from its sale are exempt from sales and use tax.

**Facts**

Petitioner sells Mirena to healthcare providers, who in turn prescribe it and insert it in their patients. Mirena is a levonorgestrel-releasing intrauterine system indicated for intrauterine contraception (birth control) and/or the treatment of menorrhagia (heavy menstrual bleeding).

Levonorgestrel is a synthetic progestogen used as an active ingredient in some hormonal contraceptives. Unlike an IUD, which does not contain a drug, but uses a copper wire to release copper ions, Mirena contains a reservoir of the hormone levonorgestrel, which is released gradually into the patient's uterus. Mirena is approved by the federal Food and Drug Administration (FDA) as a drug. Both Mirena and levonorgestrel are recognized as drugs in the United States Pharmacopeia. Mirena is also listed as a drug in the Physician's Desk Reference.

The hormone levonorgestrel prevents pregnancy. Mirena performs the same function as pill or capsule contraceptives. Mirena may not be purchased by a non-practitioner. It can be obtained only by prescription and must be placed into a patient by a healthcare provider. Ultimately, the objective of the patient and healthcare provider is to obtain a measured and controlled release of levonorgestrel into the patient's body.

**Analysis**

Section 1105(a) of the Tax Law imposes sales tax on the sale of tangible personal property. Section 1115(a)(3) of the Tax Law exempts from sales and use tax drugs and medicines intended for use, internally or externally, in the cure, mitigation, treatment or prevention of illnesses or diseases in human beings, medical equipment (including component parts thereof) and supplies required for such use or to correct or alleviate physical incapacity, and products consumed by humans for the preservation of health, but not including cosmetics or toilet articles notwithstanding the presence of medicinal ingredients therein. Medical equipment (including component parts thereof) and supplies, other than drugs and medicines, purchased at retail for use in performing medical and similar services for compensation are subject to tax.

Sales tax regulation section 528.4(b) defines "drugs and medicines" as (i) articles, whether or not a prescription is required for purchase, which are recognized as drugs or medicines in the United States Pharmacopeia, Homeopathic Pharmacopeia of the United States, or National Formulary, and intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans; and (ii) articles (other

than food) intended to affect the structure or any function of the human body. The regulation further provides that “[t]he base or vehicle used (oil, ointment, talc, etc.) and the medium used for delivery (disposable wipe, syringe, saturated pad, etc.) of a drug or medicine will not affect its exempt status.” 20 NYCRR 528.4(b)(2).

Because Mirena is classified as a drug by the United States Pharmacopeia, it is a drug for purposes of Tax Law section 1115(a)(3). This product is distinguishable from the IUD device Paragard® addressed in TSB-A-09(13)S. Paragard was classified by the FDA as a medical device, not as a drug. It was not listed as a drug in the United States Pharmacopeia. While the sales tax regulations provide that a birth control device commonly known as an IUD is medical equipment (example 4 in 20 NYCRR 528.4(e)), this regulation does not encompass a device that contains a drug as classified by the United States Pharmacopeia.

Federal drug statutes address the distinction between drugs and devices. Section 321(g)(1) of Title 21 of the U.S. Code defines the term “drugs” as “(A) articles recognized in the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).” Section 321(h) of Title 21 defines the term “device.” A component of this definition is that the product “does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.” Thus, because the sales tax definition of drugs and medicines is similar to the federal definition, it is highly significant that the FDA recognizes Mirena as a drug. Accordingly, Mirena should be classified as a drug for purposes of sales tax.

Because Mirena is a drug for purposes of Tax Law section 1115(a)(3), petitioner’s sales of Mirena to healthcare providers are exempt from sales tax.

DATED: March 8, 2010

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/S/  
Jonathan Pessen  
Director of Advisory Opinions  
Office of Counsel

NOTE: An Advisory Opinion is issued at the request of a person or entity. It is limited to the facts set forth therein and is binding on the Department only with respect to the person or entity to whom it is issued and only if the person or entity fully and accurately describes all relevant facts. An Advisory Opinion is based on the law, regulations, and Department policies in effect as of the date the Opinion is issued or for the specific time period at issue in the Opinion.