

Compliance Operations Series: 2026 U.S. Export Compliance Handbook — A Comprehensive Analysis of FDA, FCC, and CPSC Requirements from Product Market Access to Customs Release



In 2026, when entering the U.S. market, compliance can no longer be viewed as simply “obtaining a certificate during customs clearance.” U.S. import regulation is becoming increasingly data-driven. CBP (Customs and Border Protection) manages import



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entry, while agencies such as FDA, FCC, and CPSC regulate product market access. If you only discover upon cargo arrival that Prior Notice, FCC Authorization, CPC/GCC, or CPSC eFiling is required, the consequences may range from release delays to cargo return, destruction, or marketplace delisting.

First, Understand This: U. S. Customs Clearance Is Not Just About CBP

The entry point for U.S. import customs clearance is usually CBP, but many products are actually delayed because of intervention by Partner Government Agencies (PGAs). FDA regulates food, pharmaceuticals, medical devices, cosmetics, radiation-emitting electronic products, and more; FCC regulates radio frequency equipment; and CPSC oversees consumer product safety, especially children's products, toys, furniture, button battery products, and related goods.

Agency	Primary Focus	Common Products	Most Common Seller Mistake
CBP	Import declarations,	All imported cargo	Assuming the customs



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Agency	Primary Focus	Common Products	Most Common Seller Mistake
	HTS classification, customs valuation, country of origin, duties, release		broker is responsible for all compliance matters
FDA	Whether FDA-regulated products comply with U.S. requirements	Food, cosmetics, medical devices, radiation-emitting electronic products	Only asking whether registration or Prior Notice is required after cargo arrives in the U.S.
FCC	Whether RF equipment has completed equipment authorization	Wi-Fi devices, Bluetooth devices, wireless remote controls, certain electronic products	Treating CE or RoHS as an FCC certificate
CPSC	Consumer product safety, children's product certification, import certificates	Toys, children's products, furniture, button battery products	Lacking CPC/GCC documentation or having incomplete testing documentation

In one sentence: **CBP determines how your goods enter the United States, while U.S. regulatory agencies determine whether your products can enter and whether they can be sold.**

Conduct Product Classification Before Shipment

Many compliance issues do not start with FDA, FCC, or CPSC—they start with determining what the product actually is.

For example, a children's Bluetooth night light may simultaneously involve CPSC requirements, FCC requirements, UL/electrical safety standards, button battery warnings, packaging labels, HTS classification, and country-of-origin marking requirements.

Assessment Question	Purpose	If You Cannot Answer
Who is the product intended for?	Determine whether it is a children's product, medical-use product, food-contact product, etc.	CPSC or FDA requirements may be overlooked
Does it transmit wireless signals?	Determine FCC equipment authorization requirements	Bluetooth/Wi-Fi products cannot be treated as ordinary electronics
Does it contact the human body, enter the body, or contact skin?	Determine FDA applicability or cosmetic/medical device classification	Marketing claims may turn an ordinary product into a regulated product
Does it contain batteries, button batteries, lasers, LEDs, or radiation-emitting electronic functions?	Determine multiple regulatory requirements	Both transportation and market access may be affected
Who is the Importer of Record (IOR)?	Determines who bears import compliance	An overseas warehouse is not necessarily the

Assessment Question	Purpose	If You Cannot Answer
	responsibility	importer

If you need preliminary HTS/HS classification guidance, you may use OneCargoKit's HS Code Lookup for initial screening and then have a U.S. customs broker or compliance consultant confirm the classification. Do not directly copy China's export HS code, as the U.S. HTS classification and applicable regulatory requirements may differ significantly.

FDA: Not All Consumer Products Can Be Imported as Ordinary Goods

According to FDA guidance, products regulated by FDA include food, medical products, radiation-emitting electronic products, animal feed, tobacco products, cosmetics, and more.

When importing FDA-regulated products, FDA screens shipment data electronically before goods enter the United States and may inspect, detain, or request additional documentation when necessary.

Product Category	Common Compliance	Requirements Documents to Prepare Before Shipment
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Product Category	Common Compliance	Requirements Documents to Prepare Before Shipment
Food / Beverages / Dietary Supplements	Facility Registration, Prior Notice, labeling, ingredients, import alerts	FDA registration information, Prior Notice, English labels, ingredient list
Cosmetics	Ingredients, labeling, prohibited/restricted substances, marketing claims	INCI ingredient list, label artwork, intended-use description
Medical Devices	Device classification, registration, listing, 510(k) or exemption determination	Intended use, technical documentation, registration and listing information
Laser / LED / Radiation-Emitting Electronic Products	Radiation safety standards, product reports, or related declarations	Model information, user manual, testing/reports
Animal Feed / Pet Food	FDA and possible USDA requirements	Ingredients, labeling, manufacturer information

The most common FDA mistake is assuming that “being allowed on a marketplace platform” means “being importable into the United States.”

Marketplace approval and FDA import review are not the same system.

For example:

- A beauty device marketed with claims related to treatment, diagnosis, or disease improvement may be classified as a medical device.

- A food product without a valid Prior Notice may be detained immediately upon entry.

FCC: If It Has Wireless or RF Functions, Do Not Judge by Appearance Alone

FCC regulates radio frequency devices, meaning equipment that generates, emits, or uses radio frequency energy.

According to FCC requirements, RF devices subject to equipment authorization must comply with FCC technical standards and complete the applicable authorization procedures before importation or sale in the United States.

Product	Typical FCC Pathway	Practical Reminder
Bluetooth headsets, Wi-Fi cameras, wireless keyboards and mice	Certification	FCC ID, testing, labeling, and user manuals required
Power adapters, LED lighting products, and other products that may generate electromagnetic interference	SDoC or other applicable procedures	FCC ID may not be required, but compliance is still mandatory
Finished products containing wireless modules	Module Certification + End Product	Module certification alone is not sufficient



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Product	Typical FCC Pathway	Practical Reminder
	Evaluation	
Routers, communication equipment, surveillance equipment	FCC + possible Covered List considerations	Pay attention to security policies and authorization restrictions

FCC compliance is not achieved simply by printing the words “FCC” on the packaging.

Before selling in the United States, verify:

- Equipment authorization pathway
- FCC ID or SDoC documentation
- Labels
- Warning statements in manuals
- Responsible party information

A common mistake occurs when suppliers claim, “We have FCC certification,” but only provide a screenshot of a test report. The product model, applicant, frequency band, antenna, module, or product structure may not match.

For cross-border sellers, certification documents must correspond to the actual SKU and cannot be shared among similar models indiscriminately.

CPSC: The Most Important Preparation for 2026 Is eFiling

CPSC regulates consumer product safety.

Children's products generally require a Children's Product Certificate (CPC), while general consumer products subject to mandatory safety standards may require a General Certificate of Conformity (GCC).

According to CPSC guidance, the effective date for eFiling of certificate data for most regulated imported consumer products is **July 8, 2026**. For products entering commerce or warehousing from a Foreign Trade Zone (FTZ), the effective date is **January 8, 2027**.

Certificate	Applicable Scenario	Core Content
CPC	Children's products, generally intended primarily for children aged 12 and under	Applicable regulations, testing laboratory, manufacturing location, testing date, responsible party
GCC	General consumer products subject to mandatory CPSC regulations	Declaration and supporting basis showing compliance with applicable safety requirements
eFiling	Submission of certificate data	Electronic transmission of

Certificate	Applicable Scenario	Core Content
	for regulated consumer product imports	certificate data during the import entry process

CPSC's approach is not to require a paper certificate for every shipment.

Instead, responsible parties must be able to demonstrate compliance and provide certificates and testing evidence when requested.

After 2026, compliance data submission will move further upstream, requiring coordination among customs brokers, importers, brand owners, and manufacturers.

FDA, FCC, and CPSC Operational Workflow

Stage	FDA Focus	FCC Focus	CPSC Focus	Responsible Party
Product Selection	Food, cosmetics, medical devices, radiation-emitting electronics	RF device determination	Children's products and mandatory consumer product standards	Seller / Product Manager
Sampling	Ingredient review, intended use review, label review	Frequency bands, wireless modules, antennas	Age grading, materials, safety design	Factory / Compliance Team

Stage	FDA Focus	FCC Focus	CPSC Focus	Responsible Party
Testing	FDA applicability assessment or registration determination	FCC Certification/SDoC	CPSC-recognized laboratory testing	Factory / Laboratory
Production	Consistency between production lots and tested samples	Consistency of models, modules, and labels	Certificate coverage of production lots	Factory
Documentation	FDA Product Codes, Prior Notice, etc.	FCC document retention	CPC/GCC/eFiling data	Customs Broker / Importer
Import Entry	FDA electronic screening	CBP/FCC import requirements	Potential CPSC review	CBP/PGA
Sales	Labeling, advertising, recall obligations	Equipment authorization and marketing rules	Certificate retention and platform review	Seller / Brand Owner

How to Assess Typical Products

Many sellers are familiar with FDA, FCC, and CPSC, but do not know which agency applies to their products.

The following table can serve as a preliminary screening tool.

Product	Potential Agencies	Key Assessment Points	Shipment Recommendation
Children's Bluetooth Headphones	FCC + CPSC	Wireless transmission, children's product status, material safety	Verify FCC ID, CPC, and age labels together
LED Beauty Device	FDA + FCC (possible)	Medical claims, wireless functions, radiation-emitting features	Review marketing claims first, then conduct testing
Silicone Kitchen Spatula	CPSC / Food-contact requirements	Food-contact materials, labeling, general consumer safety	Do not rely solely on material reports
Pet Food	FDA (possible)	Ingredients, labeling, manufacturer information, intended use	Confirm food/feed regulatory pathway first
Remote-Control Toy Car	FCC + CPSC	Remote-Control Toy Car	CPC, FCC, and packaging warnings must all be compliant
Laser Pointer	FDA + possible FCC	Radiation-emitting electronic product requirements and labeling	Exercise extreme caution and confirm admissibility first

If a product falls under multiple agencies, satisfying only the easiest requirement

is not sufficient.

For example:

- A Bluetooth-enabled toy meeting FCC requirements does not automatically satisfy CPSC requirements.
- A beauty device passing electrical safety testing does not eliminate potential FDA regulatory risks.

Responsibilities of Customs Brokers, Laboratories, and Factories

The greatest source of confusion in U.S. compliance is that everyone assumes someone else is responsible.

Role	Responsible For	Should Not Be Misunderstood As
Factory	Providing accurate product information, production lot information, testing samples, labels	Automatically understanding U.S. market regulations
Laboratory	Conducting testing and issuing reports according to applicable standards	Assuming market compliance liability on behalf of the seller
Customs Broker	Import declarations and PGA data transmission	Determining whether product design is legally compliant
Importer / IOR	Primary responsibility for import declarations and compliance	Merely providing a tax identification number



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Role	Responsible For	Should Not Be Misunderstood As
Marketplace Seller	Product selection, marketing claims, certificates, recordkeeping, recall cooperation	Shifting all compliance risks to suppliers

In practice, the safest approach is to establish a SKU compliance file.

Each SKU should retain at least:

- Product photos
- Specifications
- User manuals
- Label artwork
- Test reports
- Certificates
- Factory information
- Commercial invoices
- Declaration records
- Marketplace links

U.S. regulators and marketplace auditors often do not ask, "Do you have a certificate?" They ask, "Can this certificate demonstrate compliance for this shipment?"

Three Key Compliance Considerations for Sellers in 2026

1. CPSC eFiling Will Move Certificate Data Upstream

Previously, many sellers treated CPC/GCC as platform-review documents and did not necessarily transmit them during importation.

After 2026, the compliance data chain for regulated consumer product imports will become much more direct.

2. Low-Value Shipments Do Not Mean Low Compliance Risk

Even small parcels may be reviewed if the product is regulated by FDA, FCC, or CPSC.

Do not treat commercial imports as personal shipments simply because they are low-value or shipped by parcel service.

3. Marketing Claims Can Change Product Classification

A standard massager promoted as “treating pain” or “improving disease conditions” may trigger more complex regulatory requirements.

Similarly, a toy marketed through images and descriptions clearly aimed at children cannot avoid CPSC requirements simply by omitting the words “children’s product.”



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Internal Division of Responsibilities for Cross-Border

Teams

Team	Recommended Actions
Product Selection	Conduct FDA/FCC/CPSC preliminary screening before listing
Procurement	Require factories to provide reports and certificates matching actual models
Operations	Control marketing language and avoid medical or children's product misrepresentation
Logistics	Confirm importer, HTS classification, and PGA data before shipment
Finance	Include testing, certification, return shipment, and destruction risks in cost calculations
Customer Service	Promptly escalate safety complaints to the supply chain

U.S. compliance is not the responsibility of a single department. It is a risk-control system jointly managed by product selection, procurement, operations, logistics, and finance.

Common Misconceptions

Misconception 1: Having CE Certification Means the Product Can Enter the United States

CE belongs to the EU regulatory system. The U.S. follows FDA, FCC, CPSC, UL/safety standards, CBP requirements, and other independent regulations.

Misconception 2: A Customs Broker Will Handle All Product Compliance Matters

A customs broker handles import declarations but does not assume responsibility for product design, testing, or market compliance.

Misconception 3: Children's Products Can Avoid CPSC Requirements by Omitting Children's References on Packaging

CPSC evaluates product design, intended use, age grading, marketing, and consumer perception.

Misconception 4: FCC Reports Can Be Used Across Different Models Without Restriction

Changes to models, modules, antennas, structures, or circuits may affect applicability.

Misconception 5: An FDA Registration Number Guarantees Customs Clearance

Registration, listing, Prior Notice, labeling, ingredients, and import alerts are separate compliance matters.

Pre-Shipment Compliance Checklist

- Confirm whether the product is regulated by one or more of FDA, FCC, or CPSC
- Confirm HTS classification, country of origin, declared value, and importer information
- For food products, determine FDA Facility Registration and Prior Notice requirements
- For medical, beauty, or health-related products, determine whether medical device classification applies
- For wireless electronic products, verify FCC ID/SDoC, model number, labeling, and user manual information
- For children's products, prepare CPC documentation and CPSC-recognized laboratory testing records
- For general consumer products, determine whether GCC is required

- Coordinate 2026 CPSC eFiling data fields with the customs broker
- Ensure marketplace marketing content does not classify ordinary products as medical, therapeutic, or children's products
- Ensure certificates, test reports, orders, invoices, and declaration records are fully traceable

Professional Summary

For exports to the United States in 2026, the key to compliance is not “obtaining a certificate before shipment,” but determining the correct regulatory pathway from the product selection stage.

FDA focuses on whether products involve food, medical devices, cosmetics, radiation-emitting electronics, and related categories.

FCC focuses on whether RF devices have completed the required authorization procedures.

CPSC focuses on consumer product safety and certification requirements.

CBP integrates all of this information into the import declaration process.

The more involved a business is in cross-border e-commerce, the more important it is to establish a comprehensive product compliance file.

Marketplace traffic can grow rapidly, but U.S. regulatory traceability moves just as quickly.

The most reliable approach is ensuring that every SKU can answer the following questions:

- Who manufactured it?
- Who imports it?
- What HTS code applies?
- Which agency regulates it?
- What testing has been completed?
- Which production lot is covered by the certification?

This article is provided for industry knowledge sharing and operational reference only and does not constitute legal, tax, product safety, or U.S. import compliance advice. For specific products, please refer to the official requirements of FDA, FCC, CPSC, and CBP, and consult your U.S. customs broker and professional compliance advisors.



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