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Review Article

Development of Chewable Tablets for Paediatric Use

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ABSTRACT


Paediatric patients frequently have difficulties with conventional solid oral dosage forms due to swallowing challenges, taste aversion, and limited dosing flexibility. Chewable tablets represent an important, age-appropriate drug delivery system that can overcome these barriers. This review critically examines the development of chewable tablets for paediatric use, focusing on formulation strategies, manufacturing processes, quality control, regulatory and safety considerations, challenges, and future innovations. Analysis of recent studies shows that effective taste masking (e.g., via ion exchange resin complexation, solid dispersion, or chocolate-based delivery matrices) is central to ensuring palatability a major factor in adherence (Usmani et al., 2023; Yoo et al., 2024). Selection of appropriate excipients (sweeteners, flavors, binders, super disintegrants) and optimization of manufacturing parameters (compression force, granulation method) significantly influence chewability, stability, disintegration, and dose uniformity (Nyamweya & Kimani, 2020; Devi & Gnanarajan, 2024). Regulatory guidance emphasizes careful screening of excipients for pediatric safety and rigorous quality evaluations (e.g., content uniformity, dissolution, stability) (Michele, Knorr, Vadas & Reiss, 2002). Case studies such as a taste masked chewable tablet of Ciprofloxacin using ion exchange resin (Usmani et al., 2023) and a chewable Prednisolone formulation using a chocolate-based delivery system (Yoo et al., 2024) demonstrate feasibility. Emerging trends include the use of 3D printing for individualized pediatric dosing (e.g., chewable Dexamethasone tablets in cancer care) (2025), advanced taste masking technologies, and “smart” chewables. The review underscores that chewable tablets, when carefully designed and evaluated, hold great promise to improve therapeutic outcomes, dosing compliance, and quality of life in paediatric patients.

INTRODUCTION

Paediatric formulations are medicinal dosage forms tailored to meet the physiological, developmental, and behavioral needs of children

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including infants, toddlers, and adolescents. These formulations must account for factors such as swallowing ability, taste perception, dose flexibility, and safety of excipients (Michele et al., 2002; Antil, Dahiya & Tomar, 2023).

A chewable tablet is an oral solid dosage form intended to be masticated (chewed) and then swallowed, rather than swallowed whole. According to a comprehensive analysis, chewable tablets are designed to “disintegrate smoothly in the mouth ... with a pleasant taste and smooth texture upon decomposition” (Patil, Yadav & Jain, 2024). Such a dosage form is particularly valuable in paediatric patients who struggle with conventional tablets or capsules, or who are averse to syrups for taste or convenience reasons.

The importance of age-appropriate drug delivery cannot be overstated. Children are not “small adults” their swallowing reflex, taste thresholds,

and ability to tolerate excipients differ. Moreover, noncompliance due to unpleasant taste or swallowing difficulty remains a major concern in pediatric therapeutics. Chewable tablets thus offer a potentially ideal balance: the convenience and stability of solids with the ease of intake and palatability more akin to liquids. However, developing chewable tablets for paediatric use presents unique challenges: ensuring accurate dosing for small or variable body weights, achieving acceptable taste (palatability), ensuring safety of excipients, avoiding choking hazards, and maintaining stability over shelf life.

This review systematically explores these aspects: advantages, formulation considerations, manufacturing techniques, quality evaluation, regulatory and safety considerations, challenges, and future directions integrating data from recent peer-reviewed studies.

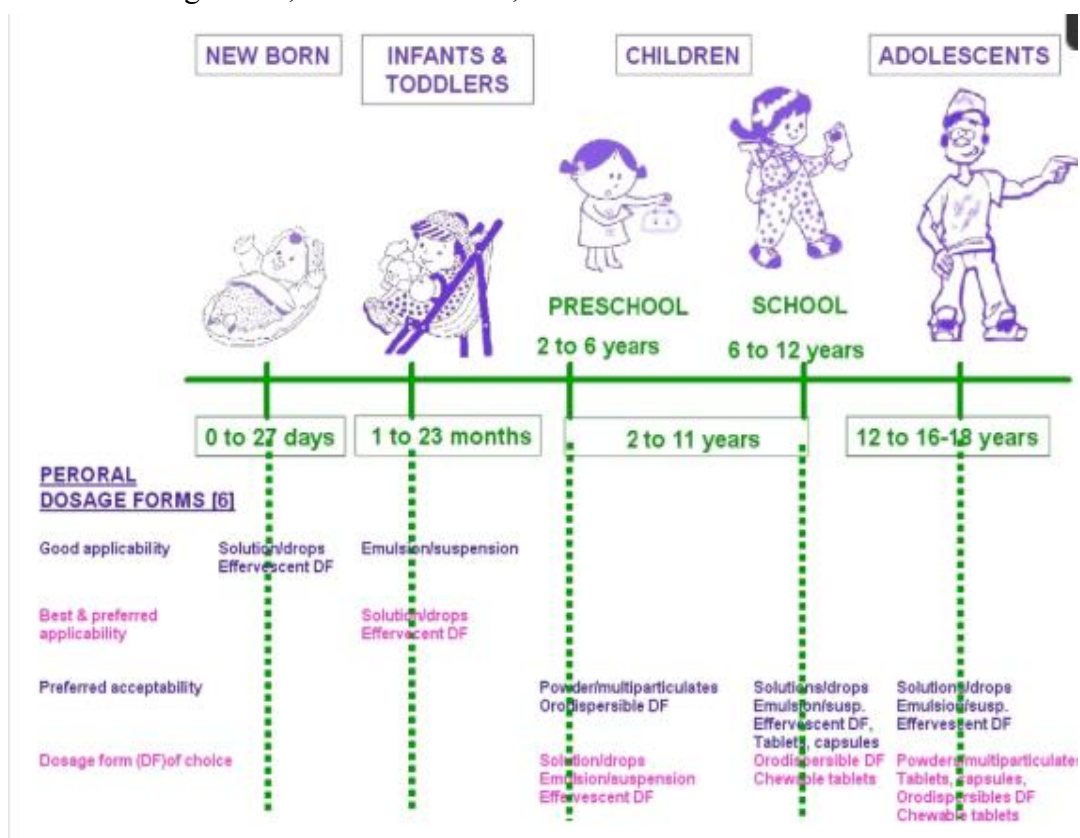


Figure 1. Age groups within the pediatric population and indication of peroral dosage forms applicability and preferences per age.

Advantages of Chewable Tablets

Patient acceptability and improved compliance

Chewable tablets are easier for children to take than conventional solid tablets because they circumvent swallowing difficulties. As noted by Patil, Yadav & Jain (2024), chewable tablets are designed for masticating “between the teeth before ingestion,” which improves acceptability in both paediatric and geriatric populations. Moreover, because chewable tablets can be flavored and sweetened, they offer a pleasant mouthfeel, helping to overcome taste aversion (Antil et al., 2023).

A systematic review focusing on pediatric safety of chewable tablets concluded that chewable tablets “provide a safe, well-tolerated alternative” and are generally suitable for children aged two years or older (Michele, Knorr, Vadas & Reiss, 2002).

Better stability compared to liquid formulations

Liquid formulations (syrups, suspensions) are often used in children, but they may suffer from limited chemical and microbial stability, require preservatives, and be sensitive to storage conditions. Chewable tablets, being solid dosage forms, tend to have superior stability, longer shelf life, and are easier to transport and store advantages especially relevant in resource-limited settings or regions with poor infrastructure. As reviewed in a formulation considerations article, chewable tablets offer the “stability advantages of solid dosage forms” while providing patient-friendly administration (Nyamweya & Kimani, 2020).

Flexibility in dosing and convenience

Chewable tablets can be manufactured in various strengths. When scored, they allow dose adjustments, which is particularly useful in paediatrics where dosage often must be tailored according to age or weight. Furthermore, chewable tablets can often be administered without water beneficial in settings where water is unavailable or when children dislike drinking. As noted in Nyamweya & Kimani (2020), chewables enable “oral drug delivery without the need for water.”

Thus, chewable tablets offer a practical balance: the convenience of solids with the ease of administration and acceptability more akin to chewable candies or gums making them well-suited for paediatric drug delivery.

Formulation Considerations

Selection of APIs

Not all active pharmaceutical ingredients (APIs) are suitable for chewable tablet formulation. For paediatric use, APIs must be appropriate in terms of dose strength, taste profile, dose flexibility, and safety for children. Bitter or unpleasant-tasting APIs pose a significant barrier; thus, taste masking becomes critical. As noted in a chewable-tablet review, organoleptic properties of the API are “the primary concern” when designing chewables (Agilan & Kokila, 2024).

APIs used in paediatric chewable tablets often include antibiotics, vitamins/minerals, antihistamines, analgesics, or other medications needing frequent administration. The choice of API must balance therapeutic necessity, palatability, dose size, and safety profile.

Role of Excipients

Functional excipients are essential in chewable tablets. Typical excipients include:



- **Sweeteners and bulking agents:** Sugar alcohols like mannitol or sorbitol are commonly used. For instance, in formulations of chewable tablets of steroids for pediatric use, sorbitol and mannitol were considered (Turk J Pharm Sci, 2023). Mannitol is often preferred because of its pleasant cooling sensation and non-cariogenic profile, making it more suitable for pediatric use (Turk J Pharm Sci, 2023).
 - **Flavors:** Natural or artificial flavoring agents (fruity, chocolate, mint) help mask unpleasant taste and make the tablet more acceptable to children (Agilan & Kokila, 2024; Nyamweya & Kimani, 2020).
 - **Binders and diluents:** These provide tablet integrity and manage compressibility. In some chewable tablets, diluents such as mannitol or sorbitol also serve as bulking agents.
 - **Lubricants:** Such as magnesium stearate used to improve manufacturability (reduce sticking), though amounts must be carefully controlled to avoid negative impact on tablet texture, chewability, or taste.
 - **Disintegrants / superdisintegrants:** Despite being chewed, inclusion of a superdisintegrant (e.g., croscarmellose sodium, crospovidone) is often necessary. This ensures that fragments or swallowed pieces rapidly disintegrate in the gastrointestinal tract for complete drug release particularly important if chewing is incomplete. As discussed in the chewable-tablet review by Nyamweya & Kimani (2020), disintegration and dissolution remain critical quality attributes.
- Because many APIs are bitter or have unpleasant taste, effective taste-masking is often indispensable. Several techniques have been employed successfully:
- **Ion-exchange resin complexation:** This is among the most promising for pediatric chewables (Usmani et al., 2023; Swati Mutha et al., 2022). For example, in a chewable tablet formulation of Ciprofloxacin hydrochloride, complexation with a weakly acidic cation-exchange resin (Kyrion T-134) resulted in taste-masked resin-drug complexes with 99.05% drug loading. The optimized chewable tablets exhibited minimal disintegration time and over 99% drug release within 30 minutes. PBPK modeling supported suitability for pediatric use (Usmani et al., 2023). Similarly, in a chewable tablet formulation of Lisdexamfetamine dimesylate (LDX), complexation with resin provided masking efficiency > 96% in saliva, and complete drug release within 15 min in acidic medium (Zhu et al., 2023).
 - **Matrix or chocolate-based delivery systems:** For APIs with very unpleasant taste (e.g., steroids), matrix-based carriers have been used. A recent study by Yoo et al. (2024) developed a chocolate-based chewable tablet of Prednisolone sodium phosphate for pediatric use. Their optimized tablet released > 80% of drug load within 20 min in 0.1 M HCl and achieved significantly better taste scores than the commercially available syrup (mean taste score 7.08 ± 2.40 vs. 5.60 ± 2.33 , $p = 0.03$). Over half of the adult volunteers preferred the chewable tablet over the syrup (Yoo et al., 2024).

Taste-Masking Techniques

- **Solid dispersions / coating / microencapsulation:** These techniques embed or coat the API in polymeric or lipid



matrices, reducing direct contact with taste receptors in the oral cavity. The use of such methods is discussed in general chewable-tablet formulation reviews (Nyamweya & Kimani, 2020; Devi & Gnanarajan, 2024). For example, in the chewable tablet development of steroids (Turk J Pharm Sci, 2023), polymeric carriers and binders were optimized to balance palate, compressibility, and disintegration.

Because chewable tablets are subject to mechanical stress (chewing), coatings must be robust or alternative methods (resin complexation, matrix embedding) are often preferred to ensure taste masking persists until swallowing.

Role of Superdisintegrants:-

Although chewable tablets are meant to be chewed, inclusion of superdisintegrants (e.g., croscarmellose sodium, crospovidone) remains important. They ensure that fragments or swallowed pieces disintegrate rapidly in the GI tract, ensuring complete drug release and minimizing variability due to incomplete chewing. As noted in general reviews, disintegration and dissolution remain critical even for chewables (Nyamweya & Kimani, 2020; Antil et al., 2023).

Manufacturing Techniques

Several manufacturing techniques are used in producing chewable tablets choice depends on API properties, taste-masking requirements, and desired tablet characteristics.

- **Direct Compression:** This remains the most straightforward and cost-effective method when powders (API + excipients) have good flow and compressibility. For taste-masked APIs (e.g., resin complexes), direct compression is often feasible because the

complexed drug exhibits acceptable compressibility and flow (Zhu et al., 2023). For example, in the LDX chewable tablet study, the authors used a direct-compression approach after taste masking via resin complexation (Zhu et al., 2023).

- **Wet Granulation:** Used when powder flow or compressibility is poor, or when taste-masking requires binding / embedding of drug into a granule matrix before compression. This method can also allow better distribution of excipients like binders, sweeteners and flavors.
- **Melt Granulation / Melt Compression:** For some formulations, melt granulation has been employed. In a chewable tablet of Paracetamol, melt granulation (with excipients such as Arabic gum, starch, agar, and mannitol) produced tablets with a “chewy texture.” In that study, 50% of drug was released within 4 minutes (fragmented form), and 100% within 30 minutes; the intact tablet released nearly 90% of drug over 2 hours (Paracetamol chewable tablets, 2021). This method can be advantageous when taste masking via embedding or matrix formation is desired.
- **Emerging 3D Printing (Additive Manufacturing):** A novel and promising approach is 3D printing. A recent 2025 study developed 3D-printed chewable tablets of Dexamethasone for pediatric oncology using semi-solid extrusion (SSE). The tablets allowed individualized dosing, had acceptable mass & content uniformity (RSD 0.75% and 99.35% \pm 2.92%, respectively), and disintegration times ranged from about 96 s (for 2 mg dose) to 733 s (for 12 mg dose). The tablets achieved complete drug release within 2 hours and demonstrated substantial bitterness reduction compared to conventional

tablets (2025). This shows that 3D printing enables personalized, child-appropriate chewables with precise dosing and taste masking.

During manufacturing, process optimization is critical: balancing hardness (too hard = poor chewability; too soft = friability), friability, disintegration time, and ease/comfort of chewing. As highlighted in a formulation-technique review, chewable tablet development must carefully evaluate sensory characteristics, chewability, and drug release (Nyamweya & Kimani, 2020).

Quality Evaluation Parameters

To ensure safety, efficacy, and acceptability of paediatric chewable tablets, rigorous quality evaluation is mandatory. Key parameters include:

- Physical tests:** Hardness (or breaking force), friability, thickness, weight variation to assure uniformity, mechanical integrity, and safe handling. As discussed by Nyamweya & Kimani (2020), these parameters are foundational for chewable tablets.
- Disintegration and dissolution testing:** Especially important if fragments or swallowed pieces remain. In the ciprofloxacin chewable tablet study, optimized tablets exhibited > 99% drug release within 30 min. (Usmani et al., 2023) For the paracetamol chewable tablet (melt granulation), fragmented tablets released 50% within 4 min and 100% within 30 min; intact forms released ~90% over 2 hours (Paracetamol chewable tablets, 2021). The chewable prednisolone tablets (chocolate-based) released > 80% drug within 20 min in 0.1 M HCl (Yoo et al., 2024). These dissolution profiles indicate that chewables when properly formulated can meet pharmacopeial dissolution criteria.
- Content uniformity / Assay:** Ensuring each tablet contains correct API dose is especially critical in paediatrics, where dosing inaccuracies may have larger clinical impact. In the 3D-printed dexamethasone chewables, content uniformity ($99.35\% \pm 2.92\%$) was demonstrated (2025). In the ciprofloxacin chewable study, drug loading of resin complex was 99.05% (Usmani et al., 2023).
- Stability studies:** According to regulatory expectations (e.g., ICH guidelines), formulations must be tested under appropriate storage conditions (temperature, humidity) over time to ensure potency, taste, and physical integrity remain acceptable. In the prednisolone chewable tablet study, the optimized PSP-based tablet was chemically stable for at least three months at ambient temperature (Yoo et al., 2024). In the amoxicillin chewable tablet study, stability for up to one year with acceptable recovery (> 91%) was reported (2021).
- Sensory / palatability evaluation:** Since palatability is a major determinant of compliance, sensory evaluation (taste, mouthfeel, aftertaste) is often conducted in adult volunteers (or older children, when ethical) as surrogate for pediatric acceptability. For example, the prednisolone chewable tablet study used a randomised crossover taste study in 25 young adult volunteers to compare taste-masked tablets vs commercial syrup (Yoo et al., 2024).
- Safety assessments:** For paediatrics, safety includes risk of choking or aspiration if tablets are not chewed properly. A review from 1966–1999 concluded that medical issues related to chewable tablets (aspiration, choking) were extremely rare, and overall chewables “provide a safe, well-tolerated alternative” for



children ≥ 2 years (Michele et al., 2002). Compliance with safety and quality standards is thus a fundamental requirement.

Regulatory and Safety Considerations

Regulatory guidance plays a vital role in pediatric chewable tablet development. As a review of chewable tablets notes, formulation must consider sensory characteristics, chewability, and drug release evaluating whether chewable administration is clinically acceptable (Nyamweya & Kimani, 2020).

From a safety standpoint, the long-cited review by Michele, Knorr, Vadas & Reiss (2002) compiled existing data (1966–1999) and found that chewable tablets are generally safe and well tolerated; serious problems such as aspiration or choking are extremely rare given proper chewing and patient age ≥ 2 years.

Moreover, when selecting excipients (sweeteners, flavoring agents, binders, disintegrants), special attention must be given to pediatric safety. Excipients acceptable for adults may not always be safe for children especially in terms of metabolic load, allergenicity, dental health (e.g., non-cariogenic sweeteners), or GI tolerability. As noted in general reviews, excipient choice and safety evaluation should be integral to pediatric chewable development (Devi & Gnanarajan, 2024; Nyamweya & Kimani, 2020).

Ethical considerations also impact sensory/palatability studies: for children, parental/guardian consent and ethical oversight are required; therefore many studies use adult volunteers as proxies, though this may not fully reflect paediatric taste perception. This limitation must be acknowledged during development.

Regulators may also demand content uniformity, batch-to-batch reproducibility, stability data (shelf life), and documentation that chewable tablets are appropriate for the intended pediatric age group (e.g., ≥ 2 or ≥ 3 years), with acceptable risk/benefit profile.

Challenges and Limitations

Despite their advantages, chewable tablets for paediatric use face several challenges and limitations:

- **Palatability and taste-masking limitations:** Many APIs have intensely bitter or unpleasant taste. While techniques like ion-exchange resin complexation or chocolate-based matrices may mask taste, effectiveness can vary. Mechanical stress from chewing may break coatings or expose drug to taste receptors, reducing masking effectiveness (Nyamweya & Kimani, 2020; Yoo et al., 2024). For certain APIs, achieving robust taste-masking that withstands chewing remains difficult.
- **Variability in chewing behaviour:** Chewing ability, thoroughness, and swallowing skill vary widely among children (depending on age). Some children may swallow parts without chewing adequately, leading to sub-optimal dissolution or dose variation. Even with superdisintegrants, incomplete chewing may affect bioavailability. As such, formulation must account for worst-case scenarios.
- **Safety choking or dental issues:** If tablets are too hard, large, or improperly chewed, they may pose choking hazards, especially in younger children. Moreover, repeated chewing of hard tablets may stress dental health or jaw muscles. Although a safety review found aspiration or choking incidents rare (Michele

et al., 2002), caution is warranted, and chewables are generally recommended only for children able to chew reliably (often ≥ 2 years).

- **Excipients' acceptability and safety:** Some sweeteners or flavoring agents may not be ideal for repeated long-term use in children. For example, sugar-based sweeteners may raise concerns about dental caries; other synthetic sweeteners or flavors may carry allergenic or metabolic concerns. Thus, careful excipient selection and safety evaluation is critical (Devi & Gnanarajan, 2024; Nyamweya & Kimani, 2020).
- **Manufacturing challenges and scale-up:** What works in lab-scale or pilot-scale may not

directly translate to commercial manufacturing. Maintaining uniformity, taste-masking robustness, stability, and batch-to-batch consistency especially when using complex techniques (resin complexation, matrix embedding, 3D printing) can be difficult. In addition, regulatory requirements demand rigorous quality control, which may increase cost and complexity.

- **Age-range limitations:** Chewable tablets may not be suitable for very young children (infants, infants below 2 years), due to chewing inability, choking risk, or inappropriate excipient load. This restricts their use to older children (often ≥ 2 –3 years), limiting broader pediatric coverage.



Figure 2. A summary of the factors impacting pharmacotherapy practice and the development of therapeutics aimed at pediatric patients.

Future Trends and Innovations

Advances in technology and pharmaceutical sciences are opening new pathways for the

development of pediatric chewable tablets. Some promising trends:

- **3D printing / Additive manufacturing for personalized pediatric dosing:** A groundbreaking study published in 2025 reported the development of 3D-printed chewable tablets of dexamethasone using semi-solid extrusion (SSE) for pediatric oncology use. The method allowed precise control over dose (from 2 mg to 12 mg) and tablet mass, with excellent content and mass uniformity ($99.35\% \pm 2.92\%$; RSD 0.75%), acceptable disintegration times, complete drug release within 2 h, and significantly reduced bitterness (2025). This illustrates the potential of 3D printing to enable individualized dosing particularly important in pediatric medicine where dose often depends on body weight or age.
- **Advanced taste-masking technologies:** Ongoing research is refining techniques such as ion-exchange resin complexation, solid dispersions, microencapsulation, pH-sensitive coatings, and matrix-based systems (e.g., chocolate-based delivery systems) to improve palatability while maintaining mechanical robustness under chewing (Usmani et al., 2023; Yoo et al., 2024; Turk J Pharm Sci, 2023). Further research into novel polymers, lipids, or biocompatible matrices, possibly with sustained-release or controlled-release features, could expand the utility of chewables.
- **“Smart” / multi-functional chewables:** In future, chewable tablets may be combined with technologies such as dose-tracking, time-released delivery, or even sensor-based feedback for adherence monitoring. Personalized chewable tablets, combined with digital health tools, could allow clinicians to

tailor therapy and monitor adherence in pediatric patients.

- **Regulatory and formulation frameworks adapting to pediatric needs:** As more data accumulate on excipient safety, taste masking, and pediatric adherence, regulatory authorities likely will update guidance to encourage development of child-appropriate chewables and support modern manufacturing techniques like 3D printing. Additionally, adoption of quality-by-design (QbD) approaches (as used in LDX chewable development, Zhu et al., 2023) could streamline development and ensure robustness.
- **Broader application beyond traditional drugs:** Chewable tablets may expand beyond antibiotics or analgesics to nutritional supplements, vitamins/minerals, multivitamins, probiotics, or even biologics (if formulations allow). Their stability, ease-of-use, and acceptability make them attractive for long-term therapies or preventive regimens in pediatric populations (Nyamweya & Kimani, 2020; Antil et al., 2023).

CONCLUSION

Chewable tablets represent a highly promising dosage form for paediatric patients, effectively addressing many of the challenges associated with conventional oral dosage forms — including swallowing difficulties, taste aversion, dosing flexibility, and stability. As evidenced by recent studies (Usmani et al., 2023; Yoo et al., 2024; 2025 3D printing study), careful formulation design — including appropriate API selection, safe and effective excipients, robust taste-masking strategies, and optimized manufacturing processes can yield chewable tablets that meet pharmacopeial standards for dissolution, content uniformity, disintegration, and palatability.



However, challenges remain particularly in ensuring consistent performance across patients of different ages and chewing behaviours, managing excipient safety, avoiding choking risk, and scaling up manufacturing while preserving taste-masking and stability.

Looking ahead, emerging technologies such as 3D printing, combined with advanced taste-masking and formulation strategies, offer exciting possibilities for personalized pediatric therapy. With continued research, rigorous quality control, and appropriate regulatory oversight, chewable tablets have the potential to become a mainstay of pediatric drug delivery improving therapeutic outcomes, adherence, and quality of life for children worldwide.

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